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ANNEX 1

ANNEX

to the

Commission Implementing Decision

on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2024

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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 caused an unprecedented health crisis across the world, 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 public health emergency and 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 threats to health through prevention, preparedness and response to such 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, as main financial instrument to fund the Union health initiatives, is implemented through annual work programmes. On 24 June 2021 the Commission adopted the 2021 work programme, on 14 January 2022 the Commission adopted the 2022 work programme and on 21 November 2022 the Commission adopted the 2023 work programme. Three amendments have been adopted on 12 April 2022², on 25 July 2022³ and on 25 July 2023⁴, to clarify the appropriate management mode for pillar assessed organisations, entities entrusted by the Commission with budget implementation tasks, and to add new actions.

The EU4Health Programme supports the implementation of Union priorities such as the fight against the COVID-19 pandemic, the activities of the Commission's Health Emergency Preparedness and Response Authority ('HERA'), the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, and the implementation of Union health legislation. The EU4Health Programme supports the extended mandates of the European Medicines Agency

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).

² C(2022) 2470 final.

³ C(2022) 5436 final.

⁴ C(2023) 5052 final.

(‘EMA’)⁵ and the European Centre for Disease Prevention and Control (‘ECDC’)⁶ and, once adopted, will support the implementation of the Health Union Package, in subsequent work programmes. The Programme should also contribute to the objectives set out in the Commission communication ‘The European Green Deal’⁷.

The EU4Health work programme for 2024 consists of four overarching ‘strands’: (1) crisis preparedness; (2) health promotion and disease prevention; (3) health systems and healthcare workforce; and (4) digital. Cancer is considered as a transversal strand.

In particular, the EU4Health work programme 2024 will amongst others address health-related issues as a consequence of the COVID-19 pandemic and of Russia’s war of aggression against Ukraine, supporting persons displaced from Ukraine. It will also support emerging policy initiatives with a special attention on mental health, global health, the developments in digital health and medicinal products and it will address actions related to the adopted Council recommendation on a new EU approach on cancer screening⁸. The work programme will also address the challenges identified in the Commission Communication ‘Addressing medicine shortages in the EU’⁹, especially to boost Europe’s capacity to produce and innovate in the manufacturing of critical medicines and ingredients and will allocate an indicative budget up to EUR 133 million.

To optimise the added value and impact from investments funded wholly or in part through the budget of the Union, the Member States will implement the EU4Health Programme in overall consistency, synergy and complementarity with other Union programmes¹⁰, policies, instruments and actions, such as Horizon Europe. Through its EU Mission on Cancer¹¹, Horizon Europe will contribute to the implementation of some of the Europe’s Beating Cancer Plan flagship initiatives and actions. The EU4Health work programme is aligned with the goal of the proposed Strategic Technologies for Europe Platform (‘STEP’) to support investments in companies that contribute to preserving a European edge on critical biotechnologies. Reaping the full benefits of biotechnology can help the EU economy grow in respect of priorities such as sustainable development, public health, and environmental protection. This work programme sets out objectives and actions, including the resource allocation, for the implementation of the EU4Health Programme in 2024. In pursuing those actions, Member States will consider the needs of people in vulnerable situations, the reduction of inequalities in the provision of

⁵ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p.1).

⁶ Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 31, 6.12.2022, p.1).

⁷ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions the European Green Deal. [COM \(2019\)640 final](#)

⁸ COM (2022) 474 final.

⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. [COM \(2023\)672 final](#)

¹⁰ For example: the Digital Europe programme, the Horizon Europe programme, the Union Civil Protection Mechanism and in particular its European reserve of additional capacities (the RescEU reserve), the Emergency Support Instrument, the European Social Fund Plus, the European Regional Development Fund, the Recovery and Resilience Facility, and Erasmus+ programme and the European Solidarity Corps Programme.

¹¹ European Mission – Cancer – Implementation Plan.

healthcare, in particular in rural and remote areas, including in the outermost regions¹², for the purposes of achieving inclusive growth and a gender sensitive approach, where relevant.

On 7 June 2023, the Commission adopted the Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health¹³ which is the starting point for a new approach which is more than just health. The approach involves areas such as education, digitalisation, employment, research, urban development, environment and climate. This work programme will support the implementation of the flagship actions referred to in the Communication on a comprehensive approach to mental health and any other initiatives on mental health within the framework of the ‘Healthier Together - EU Non- Communicable Diseases’ initiative.

In accordance with Article 13 of Regulation (EU) 2021/522, the Commission intends to provide funding to eligible legal entities from Member States, third countries associated to it, or listed in the annual work programme, entities 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 ‘Member States’ authorities’ means ‘competent authorities responsible for health in the Member States or in third countries associated to the EU4Health programme’.

With regard to third countries, their participation in actions under this work programme will be subject to compliance of their respective national systems with the Union legislation relevant to the specific action (such as Regulation (EU) 2016/679 of the European Parliament and of the Council (the ‘General Data Protection Regulation’)¹⁴ when treatment of personal data is involved).

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 966/2012,¹⁵ 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.

¹² EU outermost regions located in the Atlantic and Indian Oceans, in the Caribbean basin and in Latin America.

¹³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health. [COM\(2023\)298 final](#).

¹⁴ 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](#)).

¹⁵ [OJ L 193, 30.7.2018, p. 1](#).

BUDGET OVERVIEW FOR 2024

Based on 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 2024 is indicated in Table 2.

TABLE 1: BUDGET LINES

| BUDGET LINES | 2024 (in EUR) |
|--------------|---------------------------|
| 06 06 01 | 726 723 832 ¹⁶ |
| TOTAL | 726 723 832 ¹⁷ |

The actions included in the annual work programmes can be implemented in direct (in the form of grants and procurement) and indirect management either by the Commission or by the Health and Digital Executive Agency ('HaDEA') depending on the specific actions in compliance with the rules set out in Regulation (EU, Euratom) 2018/1046.

Grants¹⁸ are financial contributions by way of donation by the Commission 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 or an aim of general interest for the Union (operating grants).

Procurement¹⁹ 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 | 2024 Budget (in million EUR) |
|-----------------------------------|------------------------------------|
| Direct management | 677.7 |
| of which grants | 355.9 |
| of which procurement | 318.4 |
| of which for other expenditure | 3.4 |

¹⁶ Subject to the availability of the appropriations provided for in the draft general budget of the Union for 2024, following the adoption of that budget by the budgetary authority of the Union or as provided for in the system of provisional twelfths.

¹⁷ Excluding EFTA contributions with an estimated amount of EUR 25 726 024 for 2024, representing 3.54% of the EU4Health budget.

¹⁸ Articles 2(33) and 180(2) of Regulation (EU, Euratom) 2018/1046.

¹⁹ Article 2(49) of Regulation (EU, Euratom) 2018/1046.

| | |
|---|---------------------------|
| Indirect management (contribution agreements) | 74.7 |
| TOTAL | 752.4²⁰ |

For the Commission, the implementation of actions is managed directly by the Directorate-General for Health and Food Safety ('DG SANTE') or by the 'HERA' unless specified otherwise.

For actions implemented by pillar-assessed entities, the Commission will entrust them with budget implementation tasks via the conclusion of contribution agreements through indirect management mode.

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

TABLE 3: BUDGET BY ACTION AREAS

| STRANDS AND AREAS OF ACTION | 2024 budget (in EUR) |
|--|--------------------------------|
| 1. CRISIS PREPAREDNESS (CP) | 485 517 000 |
| HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA) | 470 817 000 |
| TACKLING ANTIMICROBIAL RESISTANCE ²¹ | 1 600 000 |
| IMPLEMENTATION OF THE REGULATION ON SERIOUS CROSS BORDER THREATS TO HEALTH | 12 600 000 |
| STERILE INSECT TECHNIQUE AS A TOOL TO ELLIMINATE THE YELLOW FEVER MOSQUITO (AEDES AEGYPTI ON CYPRUS) | 500 000 |
| 2. HEALTH PROMOTION AND DISEASE PREVENTION (DP) | 70 900 000 |
| TOBACCO CONTROL POLICY | 2 500 000 |
| NON-COMMUNICABLE AND COMMUNICABLE DISEASES ²² | 45 000 000 |
| MENTAL HEALTH CHALLENGES ²³ | 10 000 000 |
| EUROPEAN ENVIRONMENT AGENCY | 400 000 |
| OPERATING GRANTS FOR HEALTH NGOS | 9 000 000 |

²⁰ This amount takes the EFTA contribution into account.

²¹ Including contribution agreements with WHO and OECD.

²² Including a contribution agreement with OECD and Cancer-related actions.

²³ Including a contribution agreement with UNICEF.

| | |
|---|--------------------|
| EU4HEALTH NATIONAL FOCAL POINTS | 2 000 000 |
| SUPPORTING LONG-COVID PATIENTS: INSIGHTS AND ACTION | 2 000 000 |
| 3. CANCER (CR) | 117 600 000 |
| STRENGTHENING DIGITAL CAPABILITIES | 20 000 000 |
| PERSONALISED CANCER MEDICINE ²⁴ | 30 900 000 |
| PAEDIATRIC PALLIATIVE CARE | 14 500 000 |
| INTEGRATION OF CANCER IMAGES INTO THE FEDERATED PAN-EUROPEAN INFRASTRUCTURE TO FOSTER SCREENING PROGRAMMES | 8 000 000 |
| EUROPEAN GUIDELINES AND QUALITY ASSURANCE SCHEME FOR GASTRIC CANCER SCREENING AND CARE | 6 500 000 |
| HEALTH LITERACY FOR CANCER PREVENTION AND CARE. | 5 000 000 |
| CANCER REGISTRY DATA FEEDING INTO THE EUROPEAN CANCER INFORMATION SYSTEM | 13 000 000 |
| RADIATION SAFETY AND QUALITY OF COMPUTED TOMOGRAPHY IMAGING OF CHILDREN AND YOUNG ADULTS | 3 000 000 |
| PSYCHOSOCIAL SUPPORT AND REHABILITATION FOR CHILDREN AND THEIR FAMILIES IN PAEDIATRIC ONCOLOGY CLINICS IN MEMBER STATES AND COUNTRIES ASSOCIATED TO THE EU4HEALTH PROGRAMME | 7 400 000 |
| EU NETWORK OF YOUTH CANCER SURVIVORS | 5 000 000 |
| PROVISION OF CARE FOR ADOLESCENT AND YOUNG ADULT CANCER PATIENTS | 1 000 000 |
| SUPPORT FOR THE SUBGROUP ON CANCER UNDER THE EXPERT GROUP ON PUBLIC HEALTH | 500 000 |
| BOOSTING CANCER PREVENTION THROUGH MAINTENANCE OF THE EU CANCER APP. | 1 800 000 |
| SUPPORT SETTING UP NEW NETWORKS OF EXPERTISE ON CANCER AND CANCER CONDITIONS | 1 000 000 |
| 4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS) | 41 404 000 |
| REFORMING AND STRENGTHENING HEALTH SYSTEMS ²⁵ | 2 000 000 |
| PREPARATION AND IMPLEMENTATION OF THE HEALTH TECHNOLOGY ASSESSMENT REGULATION | 650 000 |

²⁴ Including direct grants to Member States and the call for proposals covering metastatic cancer.

²⁵ Including a contribution agreement with WHO Europe and Membership fee WHO EU Observatory.

| | |
|--|-------------------|
| IMPLEMENTATION OF THE PHARMACEUTICAL LEGISLATION AND STRATEGY ²⁶ | 8 516 000 |
| STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS ²⁷ | 15 278 000 |
| CROSS BORDER HEALTHCARE | 200 000 |
| IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES | 13 950 000 |
| HEALTH POLICY TRAINING | 810 000 |
| 5. DIGITAL (DI) | 25 750 000 |
| COMMUNICATION AND INFORMATION ACTIVITIES FOR THE PROPOSED EUROPEAN HEALTH DATA SPACE | 1 600 000 |
| PRIMARY USES OF HEALTH DATA IN THE PROPOSED EUROPEAN HEALTH DATA SPACE | 11 500 000 |
| SECONDARY USES OF HEALTH DATA IN THE PROPOSED EUROPEAN HEALTH DATA SPACE | 2 650 000 |
| COMPLIANCE CHECKS FOR EHDS INFRASTRUCTURES | 1 500 000 |
| PROMOTING AND DEVELOPING DIGITAL SOLUTIONS AT INTERNATIONAL LEVEL | 4 000 000 |
| PROMOTING THE UPTAKE OF ARTIFICIAL INTELLIGENCE IN HEALTH | 4 500 000 |
| 6. OTHER ACTIONS | 11 278 856 |
| CONFERENCE – PRESIDENCY OF THE COUNCIL OF EUROPEAN UNION | 200 000 |
| ORGANISATION OF CONFERENCE AND EVENTS | 450 000 |
| SCIENTIFIC COMMITTEES | 710 000 |
| HEALTH POLICY PLATFORM | 500 000 |
| COMMUNICATION ACTIVITIES | 3 370 500 |
| STUDIES | 708 356 |
| TRANSLATION SERVICES | 120 000 |
| IT RECURRENT ACTIVITIES | 4 150 000 |
| JOINT AUDIT ASSESSMENT ²⁸ | 170 000 |
| EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA) EXPERT EVALUATORS | 400 000 |
| HERA IMPACT ASSESSMENTS | 500 000 |

²⁶ Including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Pharmaceutical Regulators Programme (IPRP).

²⁷ Including a contribution agreement with the Council of Europe/European Directorate for the Quality of Medicines & HealthCare (EDQM).

²⁸ Including the International Medical Device Regulatory Forum.

ELIGIBILITY, SELECTION AND AWARD CRITERIA FOR ACTION GRANTS

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

Grant applicants and partners shall 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 bodies²⁹.

The Commission will assess proposals 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-financing³⁰. 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 costs³¹. In the case of direct grants awarded without a call for proposals to European Reference Networks ('ERNs') and to other transnational networks set out in accordance with Union law referred to in Article 13(6) of Regulation (EU) 2021/522, such grants may be up to 100 % of eligible costs in accordance with Article 8(4) of Regulation (EU) 2021/522.

The exceptional utility assessment and ranking of proposals shall be done by the contracting authority 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 from the list of performance indicators listed in Annex II to Regulation (EU) 2021/522. Those indicators are complemented by a more comprehensive set of indicators as part of the performance monitoring and evaluation framework of the EU4Health Programme. For each action, the Commission will include meaningful action-level indicators in the contracts to be signed, which may be complemented by indicators defined by the beneficiaries and agreed by the Commission. Beneficiaries will collect data for measuring and monitoring the progress of implementation including with the action-level indicators and for highlighting the key results achieved. Data needs to be available for these indicators and communicated to the contracting authority on a regular basis and must be of sufficient quality and reliability; given limited resources, the collection of such data shall also be cost-efficient.

²⁹ Article 198(5), and (6), of Regulation (EU, Euratom) 2018/1046.

³⁰ Article 190(1), of Regulation (EU, Euratom) 2018/1046.

³¹ Article 8(3), of Regulation (EU) 2021/522.

A. GRANTS

ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

1. CRISIS PREPAREDNESS (CP)

CP-g-24-10 Call for proposals on the European Hub for vaccine development (HERA)

POLICY CONTEXT

Following the European Health Union proposals of 11 November 2020, the Commission established HERA through a Commission Decision on 16 September 2021.³² Overall, HERA will contribute to the development, manufacturing, procurement and distribution of medical countermeasures in the Union to allow for a better preparedness for and response to serious cross-border threats to health and emergencies – whether of natural or deliberate origin. One of HERA’s core missions is to support the development, access and uptake of medical countermeasures, including medicinal products, medical devices, *in vitro* diagnostic devices, Personal Protective Equipment (‘PPE’) and other health technologies, necessary to improve preparedness and response to serious cross-border health threats.

The COVID-19 crisis has illustrated the need to support technologies that can be rapidly adapted to ensure a rapid response in case of emergency. The development and access to prototype vaccines are an important cornerstone of pandemic preparedness and can best be achieved by bundling available excellence at Union level and interlink it with international initiatives. A decentralised hub for vaccines, involving different development centres of excellence, can bundle critical knowledge and combine it with ever-warm capacities for clinical trials in collaboration with EU clinical trial networks. In addition, the creation of vaccine prototypes should significantly speed up bringing innovative medical countermeasures to the market and ensure scaling of production and equal distribution.

This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures, with a focus on priority pathogens with pandemic potential. It implements the EU4Health Programme’s general objective of improving the availability, accessibility and affordability of crisis-relevant products (Article 3, point (c)) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to create an end-to-end European Hub for vaccine development, combining excellence in Research and Development (R&D) with industrial capacities to be launched as an open call for proposals. This call will target consortia of developers of vaccines covering expertise in development including publicly funded and industrial organisations.

The Hub will need to develop a strategic vaccines and antibodies plan for Europe, and subsequently deliver on: creating of vaccine prototypes, in particular for priority pathogens with epidemic and pandemic potential, further developing of state-of-the-art technologies that can be rapidly adapted, preparing relevant master clinical trial protocols, combining activities with clinical trial capacities and at scale production.

³² Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority ([OJ C 393I, 29.9.2021, p. 3–8](#)).

EXPECTED RESULTS AND IMPACT

This action is expected:

- a) to contribute to better preparedness and early response;
- b) to increase the availability and uptake of vaccines;
- c) to contribute to the availability of preventive measures to slow the spread of the pathogens;
- d) to expand Europe's competitiveness and strategic autonomy.

This action can be used in the future as a blueprint for other medical countermeasures, such as therapeutics, including antibodies and antitoxins.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|---|
| Call for proposals - CP-g-24-10 | Q1-Q2/2024 | EUR 102 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grant) | HaDEA | Vaccine developers including publicly funded and industrial organisations |

CP-g-24-11 Call for proposals for next-generation respiratory protection (HERA)

POLICY CONTEXT

HERA is responsible for improving preparedness and response to serious cross-border health threats through ensuring the availability and accessibility of relevant MCM. Notably, it does so by promoting research and development of medical countermeasures, as well as of the related technologies and potential solutions to market challenges. PPE, and especially respiratory protection, plays a fundamental role in saving lives in the context of public health emergencies. PPE is particularly critical in the early stages of pandemics and epidemics, before vaccines and therapeutics are developed.

At the same time, respiratory protection widely used during the COVID-19 pandemic, such as medical facemasks or FFP2 respirators, had drawbacks. For example, it did not offer adequate protection against highly transmissible pathogens like SARS-CoV-2³³ and it did not allow for comfortable multi-hour use, resulting in low adherence to protocols. Crucially, FFP2 respirators require expensive ‘fit testing’ to ensure filtration efficiency across population groups (particularly women, children, and other groups) and to ensure their indicated level of protection. It is not feasible to provide for such ‘fit testing’ before a public health emergency³⁴. Even if FFP2 respirators are fit-tested and worn correctly, their level of protection decreases significantly over time³⁵. These shortcomings are widely recognised to have exacerbated the health impact of the COVID-19 pandemic and hamper the response to future pandemics.

Through this action, HERA will support the development of next-generation respiratory PPE that address and mitigate the above-mentioned issues, ending a 30-year period of no significant innovation in the field and ultimately ensuring a more effective response to future cross-border health threats, with an all-threats approach. Through this action, HERA implements the EU4Health general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supports the innovation of such products (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to foster innovation and support development of next-generation respiratory PPE that overcomes the limitations outlined above. This would result in increased availability of enhanced medical countermeasures for pandemic preparedness and response. Applicants might develop completely new technologies or rely on reformulated designs and novel applications of existing materials and technologies. Applicants need to propose a detailed plan to design, prototype, validate and CE mark innovative, cost-effective, and sustainable next-generation respirators. To overcome the limitations outlined above, they need to offer higher levels of protection than FFP2 respirators while being universally fitting, enabling comfortable multi-hour use.

Different solutions may target different populations (e.g., clinicians, critical workers, the public, etc.). Proposals should include a dissemination and market readiness plan that ensures a market

³³ Empirical studies are unclear about whether masks provide adequate protection (see [Jefferson et al., 2023](#) for Cochrane library for an overview). Even if empirical data is ambiguous, there are strong theoretical reasons to suspect FFP2 respirators do not offer sufficient protection – see e.g., [results of a parametric analysis by Gryphon Scientific](#) suggesting exposure to SARS-CoV-2-infected individuals for less than one hour results in 50% infection risk, even if a tight-fitting N95 respirator is worn.

³⁴ [Ciotti et al., 2012](#); [Ng et al., 2022](#).

³⁵ [Mahdavi et al., 2015](#).

for the product in preparedness times – e.g., through stockpiling or active use. This plan should generate sufficient demand to set up production.

Importantly, developers also need to demonstrate feasibility for rapid production scale-up once a public health emergency materialises, possibly relying on distributed manufacturing solutions and on the use of accessible raw materials. Products should demonstrate the potential to be at a cost that will allow for a switch from the currently used PPE. To encourage sustainability, products should be reusable, less harmful for the environment and ideally foster environmentally friendly production. Proposals need to take into consideration that next generation respirators should be easy to store (e.g., occupying minimum space in stockpiles and have long expiry dates) and of simple use by the target population.

EXPECTED RESULTS AND IMPACT

This action will support bringing next generation PPE to the market to provide sustainable, universal and effective choices for the personal protection of healthcare and other essential workers, patients and the public. Superior respiratory protection will be available for stockpiling, scale-up and uptake by healthcare systems and the public in response to future pandemics or epidemics. The reduction of the use of single-use products will make the Union less vulnerable to supply chain disruptions.

Cost-effective and user-friendly next generation respirators will slowly replace regular respirators and be deployed at national, regional, and local levels, ensuring better preparedness for future pandemics and other cross-border health threats. Widely incorporating improved respirators into clinical practice will also lead to better protection for healthcare workers and patients already in preparedness times, and overall improved health outcomes.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|---|
| Call for proposals – CP-g-24-11 | Q2-Q3/2024 | EUR 20 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grants) | HaDEA | Private and public bodies active and in the field of innovation and with adequate expertise in PPE. |

2. HEALTH PROMOTION AND DISEASE PREVENTION ('DP')

NON-COMMUNICABLE AND COMMUNICABLE DISEASES

DP/CR-g-24-28 Direct grants to Member States' authorities: Cancers caused by infections, vaccine-preventable cancers and addressing communicable diseases (HIV/AIDS, Tuberculosis, Hepatitis)

POLICY CONTEXT

Cervical cancer is the second most common cancer among women aged 15 to 44 in the Union, with 33 000 cases and 15 000 deaths yearly. The major cause of cervical cancer is persistent infection with specific types of human papillomaviruses ('HPV'). Further, HPV is associated with other cancers such as anogenital or oropharyngeal cancers, affecting both women and men.

According to the European Centre for Disease Control ('ECDC')³⁶, there are an estimated 4.7 million chronic hepatitis B virus ('HBV') cases and 3.8 million chronic hepatitis C virus ('HCV') cases in the EU/EEA. Diagnosis of these infections is often missed as many of those who are infected with hepatitis B or C do not show symptoms. If left untreated, chronic infection with hepatitis B and C may progress to liver cirrhosis or cancer.

Viral hepatitis, according to ECDC data, is responsible for 55% of all liver cancer deaths, which have increased significantly over the past decades.

While Union targets are aligned with global targets when it comes to the elimination of viral hepatitis, there is still a need for specific Union-level HPV targets.

One of the flagship initiatives of Europe's Beating Cancer Plan is to support Member States' efforts to extend routine vaccination against HPV of girls and boys, to eliminate cervical cancer and other cancers caused by HPV. The objective is to vaccinate at least 90% of the Union target population of girls and to significantly increase the vaccination of boys by 2030. The upcoming Commission proposal for a Council Recommendation on vaccine-preventable cancers aims to support Member States in increasing HPV vaccination coverage rates in a gender-neutral perspective.

Further, the Europe's Beating Cancer Plan will help to ensure access to vaccination against hepatitis B and to treatments of hepatitis C associated with liver cancer. Additional challenges include prevention, access to testing, linkage to care, and monitoring and quality of surveillance data.

The Commission intends to launch in 2024 a Commission proposal for a Council Recommendation on vaccine-preventable cancers, which would focus on supporting Member States in increasing the uptake of HPV and HBV vaccination among all affected population groups.

The 2018 Council Recommendation on strengthened cooperation against vaccine-preventable diseases calls for targeted outreach to vulnerable population groups. In 2020, the Commission issued a reformed EU Roma strategic framework for equality, inclusion and participation³⁷. Vaccination can contribute to reduce inequalities in health among Roma populations in the Union.

³⁶ [World Hepatitis Day 2022 \(europa.eu\)](https://www.euro.who.int/en/health-topics/communicable-diseases/news/news/2022/04/world-hepatitis-day-2022).

³⁷ [The new EU Roma strategic framework for equality, inclusion and participation](https://ec.europa.eu/romea/romea-strategic-framework).

Since communicable diseases such as HIV/AIDS, tuberculosis and viral hepatitis continue to be an important public health challenge at Union level, they should also be addressed.

While cancer is usually considered within a non-communicable disease framework, a considerable number of cancers are caused by infections. Primary causes of cancers caused by infections are *Helicobacter pylori* ('*H. pylori*'), HPV, HBV, and HCV. *H. pylori* will be covered through actions supporting the implementation of the new Council Recommendation on cancer screening, which suggests test-and-treat strategies for *H. pylori* as a means for gastric cancer screening.

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 and has a Union added value.

The joint action will support the policy objective of reducing the burden of cancer and it will support the Europe's Beating Cancer Plan objective to ensure access to vaccination against HBV and to treatments of HCV associated with liver cancer. The joint action implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this joint action is to decrease premature morbidity and mortality caused by communicable diseases, including cancers caused by infections and vaccine-preventable cancers. This joint action can also address HIV/AIDS, tuberculosis, and viral hepatitis, including stigma and discrimination experienced by people living with HIV.

A specific objective of this joint action is to reduce cancers caused by infections, notably HPV, HBV, and HCV.

Actions contributing to this objective should build upon the deliverables of the joint action PERCH and the two supporting projects PROTECT-EUROPE and ReThink HPVaccination (covering HPV) as well as the VH-COMSAVAC project (covering HBV and HCV). The developed training, information, and campaign material as well as knowledge gained through the roll-out of testing and vaccination campaigns and programmes shall be used, further developed and adapted to national, regional or sub-population-specific contexts, if necessary. Member States may transfer and roll-out identified promising and best practices, such as those under the EU Best Practice Portal³⁸. Actions may focus on HPV, HBV or HCV, or cover more than one of the infections.

Furthermore, this joint action will support the implementation of the upcoming Council Recommendation on vaccine-preventable cancers, with the overall goal of increasing the uptake of vaccination against HPV and HBV across the Union and among all affected population groups, and by developing public health activities which contribute to the reduction of cancers caused by infections (HPV, HBV and HCV) such as:

- a) awareness-raising and provision of information and knowledge on the impact of infections as possible causes for cancer among all affected population groups;

³⁸ [Best Practices Portal](#).

- b) awareness-raising and provision of information and knowledge on the importance of HPV vaccination for girls and boys, and HBV vaccination as a key cancer prevention measure;
- c) awareness-raising and provision of information on the importance of HBV and HCV testing and treatment as well as an improved linkage to care in a cancer-prevention perspective;
- d) capacity-building for health professionals and support for patient associations.

Where relevant, activities under this joint action will address the specific needs of vulnerable population groups such as Roma populations, displaced people from Ukraine and migrants/refugees.

In particular, these activities should ensure that displaced children, (pre)adolescents and young adults (girls and boys) from Ukraine receive the HPV and HBV vaccine in accordance with the host country's vaccination strategy. Displaced children from Ukraine should be checked for their HBV vaccination status within the host country's health system.

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

EXPECTED RESULTS AND IMPACT

The expected results of this joint action include:

- a) development, roll-out and scale-up of actions that can contribute to increased awareness and knowledge of infections as possible causes for cancer across all affected population groups and of the importance of HPV vaccination for both boys and girls as a key cancer prevention measure, and of the importance of HPV, HBV and HCV testing and treatment in a cancer-prevention perspective;
- b) development of initiatives that can help reduce structural barriers to HPV and HBV vaccination for all affected population groups;
- c) identification and transfer of best or promising practices in terms of increasing the uptake of HPV and HBV vaccinations;
- d) development of initiatives that can increase health literacy on cancers caused by HPV and on HPV vaccination among boys and in LGBTQI+ communities;
- e) development of initiatives that can increase health literacy on HBV vaccinations and HBV and HCV testing and treatment among prison populations;
- f) guidance to help Member States increase the uptake of HPV and HBV vaccination among vulnerable population groups such as Roma, including through vaccination sites/hubs with easy access to vaccines;
- g) guidance to help Member States increase the uptake of HPV and HBV vaccines among displaced persons from Ukraine, including strategies for checking vaccination status and catch-up vaccination;
- h) targeted information material developed in collaboration with health professionals and health mediators;
- i) training material and sessions for health professionals on how to address the importance of HPV and HBV vaccination with patients;
- j) tools to support patient associations in terms of addressing the importance of HPV and HBV vaccination;

- k) tools to address mis- and disinformation;
- l) guidance to help Member States strengthen the monitoring of HPV and HBV vaccination uptake and to coordinate vaccination and cancer registries in respect of national legislation;
- m) development of initiatives that can address stigma and discrimination of people living with HIV;
- n) identification and transfer of best or promising practices addressing the burden of HIV/AIDS, tuberculosis, and viral hepatitis.

The expected impact is an increased uptake of HPV vaccination for both girls and boys, better awareness of the risks among target populations, an increased uptake of HBV vaccination among the vulnerable groups, and an increased uptake of HBV and HCV testing and treatment as well as improved linkage to care.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants – DP/CR -g-24-28 | Q3/2024 | EUR 20 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

3. CANCER (CR)

CR-g-24-36 Direct grants to Member States' authorities: Strengthening digital capabilities including e-health, telemedicine, remote monitoring systems, health data access and health data exchange services in cancer centres in the Union

POLICY CONTEXT

Across Europe, early-diagnosis and survival rates for cancer vary greatly due to differences in prevention policies and access to diagnosis, treatment, and care. It is predicted that by 2035 the number of deaths from cancers in Europe may increase by almost a quarter³⁹, therefore, making it the leading cause of death in Europe.

Taking this into consideration, digital transformation can bring significant benefits to the healthcare sector. Up to 30% of the world's stored data is currently generated by healthcare systems. However, the healthcare sector is lagging in realising this potential. It is a "data-rich but information-poor" industry⁴⁰.

Cancer care is one of the major disease areas that will benefit from the European Digital Strategy thanks to better exploitation of real-world data using powerful tools such as Artificial Intelligence ('AI') and High-Performance Computing. The increased use of telemedicine in healthcare is a new window of opportunity to responding to population health crises, as seen during the COVID-19 pandemic. Currently, there is much room for improvement in the deployment of digital interventions for cancer patients both at Member States and EU-level.

Despite this, barriers persist in the Union around interoperability, legal and ethical standards, governance, cybersecurity, technical requirements, and compliance with personal data protection rules. Thus, this action could reinforce the good management of digital tools complying with Regulation (EU) 2016/679 (the 'General Data Protection Regulation' or the 'GDPR'⁴¹). The proposed European Health Data Space ('EHDS') Regulation⁴², which would offer a health-specific data space embedded in the data strategy for Europe⁴³, would offer a unique opportunity to increase the use and re-use of health data for the benefit of cancer patients.

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 and has a Union added value.

This joint action will support the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, points (a) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), and (g), of Regulation (EU) 2021/522).

³⁹ [Global Cancer Observatory](#).

⁴⁰ OECD (2019), *Health in the 21st Century: Putting Data to Work for Stronger Health Systems*, OECD Health Policy Studies, [OECD Publishing](#), Paris.

⁴¹ 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 (OJ L 119, 4.5.2016, p. 1).

⁴² Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. [COM \(2020\)197](#) final.

⁴³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A European Strategy for data. [COM \(2020\)66 Final](#).

This joint action will also support the implementation of the planned EHDS and it implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, point (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the joint action is to enhance the digital capabilities of the cancer centres in the Union, particularly in Eastern Europe. The actions should focus on improving the e-health, telemedicine, remote monitoring system, health data access and health data exchange services that are in place or need to be developed in the cancer centres. This will support a better collaboration between the cancer centres by improving cancer prevention, early detection and care.

This action is relevant for the proposed EHDS. This action will contribute to the alignment of the infrastructures of cancer centres in the EU with the relevant EHDS infrastructures (MyHealth@EU and HealthData@EU). This alignment will avoid duplications and will ensure that the work conducted for the purpose of this action will complement and contribute to the broader work concerning the proposed EHDS. This action should also build upon the EHDS interoperability specifications for the European Electronic Health Record exchange Format as well as on minimum specifications for datasets to be used for research, innovation, policy making and official statistics.

This joint action will support the developing of digital capabilities for cancer centres with limited resources in the Union. It will build on the results of several EU4Health Programme projects: the Joint Action on strengthening e-health including telemedicine and remote monitoring for healthcare systems for cancer prevention and care (JA eCAN)⁴⁴, the relevant joint actions under the proposed EHDS such as "Towards a European Health Data Space" (TEHDaS)⁴⁵ or the HealthData@EU pilot⁴⁶, and the Cancer Care BEACON⁴⁷. This joint action will make use of the guidelines, protocols, and best practices, developed under the previous projects as well as linked projects such as the joint action on the EU Network of Comprehensive Cancer Centres (JA CraNE)⁴⁸ and in the context of the planned EHDS (e.g., eHealth Network guidelines), as well as the UNCAN.eu and European Cancer Patient Digital Centre projects under Horizon Europe programme.

The activities carried out in this joint action should include at least:

- a) the implementation of the cancer centres digital capabilities by reviewing the digital equipment/systems, legislative and guidelines used in e-health, telemedicine and remote monitoring systems, health data access and health data exchange services as well as compliance with the GDPR and national law and in alignment with the proposed Regulation on the European Health Data Space;
- b) the exploration of the use of the key frameworks and infrastructures of the proposed EHDS, such as health data access bodies MyHealth@EU and HealthData@EU infrastructures or the European Electronic Health Record exchange Format by cancer centres;

⁴⁴ Joint Action eCAN ([eCAN](#)).

⁴⁵ Joint Action Towards the European Health Data Space ([TEHDAS](#))

⁴⁶ [HealthData@EU Pilot](#)

⁴⁷ Cancer [Care BEACON](#).

⁴⁸ European Network of Comprehensive Cancer Centres ([JA CraNE](#))

- c) the establishment or improvement of the e-health, remote monitoring systems and telemedicine, health data access and health data exchange services particularly in Eastern Europe (e.g., pilot projects to be implemented);
- d) the development of the research activities at national, European and international level by improving the collaboration and digital capabilities among the cancer centres and their interaction with the health data access bodies that would be established in the context of the future EHDS and relevant European research infrastructures and digital platforms supporting cancer research and digital technology development;
- e) the development of the guidance tools, recommendations and protocols for the digital capabilities in cancer centres, as well as cancer patients and their families/carers guidelines or information leaflets for using e-health, telemedicine and remote monitoring systems in line with the relevant EHDS technical guidelines, specifications and best practices;
- f) the development of the collaborations between different cancer centres in the Member States and countries associated to the EU4Health Programme for developing better guidelines and ensuring best practices for using e-health, telemedicine and remote monitoring systems, health data access and health data exchange services;
- g) information and dissemination campaigns of recommendations, guidance, protocols and tools for justification and optimisation of digital tools, including e-health, telemedicine, remote monitoring systems, health data access and health data exchange services among the hospitals and medical centres in Member States;
- h) public information campaigns about the benefits, risks and care safety of e-health, telemedicine and remote monitoring systems, health data access and health data exchange services.

EXPECTED RESULTS AND IMPACT

As an expected outcome of the activities, the cancer centres will receive improved tools to ensure justification and optimisation of digital technologies, including e-health, telemedicine and remote monitoring systems, health data access and health data exchange services.

Cancer patients and their families/carers accessing e-health, telemedicine and remote monitoring services in Member States will benefit from the results of this joint action. In addition, healthcare professionals will benefit from better training materials and opportunities in digital capabilities. The results of these activities are expected to bring short-term improvements in using digital tools, including e-health, telemedicine and remote monitoring systems, health data access and health data exchange services for cancer centres. In the mid- to long-term, this is expected to translate into better collaboration and cooperation between the cancer centres in healthcare digital technologies, research, and care for cancer, and with other participants for which a role is envisaged under the planned EHDS, such as health data access bodies.

The outcomes of this joint action should also reduce discrepancies in Europe through a coordinated approach to current digital capabilities, by providing best practices for future cancer centres.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants – CR-g-24-36 | Q2/2024 | EUR 20 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

CR-g-24-41 Direct grants to Member States' authorities: Personalised Cancer Medicine

POLICY CONTEXT

Personalised Medicine⁴⁹ (PM) is an emerging field that has the potential to beat cancer. To leverage the potential of Personalised Cancer Medicine (PCM) and improve survival and quality of life when facing cancer, PCM programmes need to be widely accessible to all patients in need. There is a need for implementation of PCM by acquiring further knowledge and ensuring trans-border access to PCM trials and care for patients in Europe. Cross-border access and education are essential parts of ensuring cancer treatment outcome and quality of life (these are the main goals of Europe's Beating Cancer Plan).

Equal access to comprehensive genomic testing and matched anticancer medicines in the Union is one of the goals of the Europe's Beating Cancer Plan to reduce the unacceptable differences in cancer survival across the Union. Despite existing differences in economic status between the Member States, there should be guidelines about what the minimum of molecular diagnostics should be for a cancer patient.

In this sense, it is necessary to support public health authorities with a coordinated, harmonised, and comprehensive approach by strengthening their capacity in implementing personalised and sustainable programmes for cancer.

There is a clear need for upscaling the access to and knowledge of targeted treatment options of cancer in Europe, especially in those Member States that joined the Union after 1 May 2004, and a need for cooperation between Member States that are about to have access to these treatments, or already have (limited) access and want to expand.

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 and has a Union added value.

This joint action will support the Europe's Beating Cancer Plan objective to ensure high standards in 'Cancer diagnostic and treatment for all' and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522).

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the joint action is to strengthen the PCM network within the Union. This European network has a solid history, especially in the Netherlands and the Nordic Countries. Actions taken should in particular focus on upscaling the access to PCM within Member States, including for metastatic cancer, but also on developing stronger collaborations with the countries associated to the EU4Health Programme that have a strong interest in PCM.

This action should cover the ambition of the sixth flagship of the Europe's Beating Cancer Plan: 'Cancer diagnostic and treatment for all' initiative and will build on the results of other EU4Health Programme funded projects: the project Personalised Cancer Medicine for all Union citizens (PCM4EU)⁵⁰, the EU Cancer and Public Health Genomics platform project (CAN.HEAL)⁵¹, as well as the project for improved diagnostics and survival for all children

⁴⁹ [Personalised medicine \(europa.eu\)](https://europe.europa.eu).

⁵⁰ Personalised Cancer Medicine for all EU Citizens ([PCM4EU](https://pcm4eu.eu))

⁵¹ [Can.Heal | Building the EU genomics platform \(canheal.eu\)](https://can.heal.eu).

with Acute Myeloid Leukaemia treated within the NOPHO-DB- SHIP consortium, which is a cross-European collaboration (CHIP-AML22)⁵².

The action will make use of the guidelines, protocols, and best practices, developed by other EU-funded projects. Projects and major initiatives on personalised medicine, such as the International Consortium for Personalised Medicine (ICPerMed)⁵³, the 1+ Million Genomes Initiative⁵⁴, a European-wide foundation to accelerate Data-driven Cancer Research (EOSC4Cancer)⁵⁵, and the European Partnership for Personalised Medicine (a Europe's Beating Cancer Plan action)⁵⁶ should also be considered.

The activities carried out in this joint action should include at least:

- a) extending the PCM access to already existing infrastructures, including in associated countries;
- b) improving the access to PCM to Member States that have limited resources e.g., Eastern European countries;
- c) linking the PCM to the European Reference Networks– strengthening the structure needed for the implementation of PCM as a part of the healthcare system;
- d) facilitating cross-border access to genomic testing and PCM, as there is a clear need for cross-border access to promising PCM treatments for patients who would be in the condition to travel;
- e) developing and promoting guidance for metastatic cancer patients using best practices in healthcare; (this should include the development of national guidance, protocols and tools for optimisation of personalised cancer medicine, including for metastatic cancer, that will be consistent with Union legislation, recommendations and guidelines. These will be developed after reviewing the results of other similar projects under the EU4Health and/or Horizon Europe programmes);
- f) upscaling of the EU Cancer and Public Health Genomics Platform in alignment with the European Genomic Data Infrastructure⁵⁷;
- g) providing specific education and training for health professionals to advance the implementation of genetic testing and personalised medicine in oncology by using the models for training and educational interventions on oncogenomic and personalised cancer medicine, including for metastatic cancer;
- h) establishing strategies for the implementation of telegenetics and remote genetic counselling in Europe to personalise public healthcare;
- i) improving the collaboration between different institutions/organisations from national, European and international level that are offering personalised cancer medicine e.g., the European Medicine Agency, Horizon Europe co-funded projects on personalised cancer medicine;
- j) setting up information and dissemination campaigns of recommendations, guidance, protocols and tools for personalised cancer medicine among the concerned hospitals and medical centres in all Member States;
- k) setting up information campaigns for citizens about the benefits and challenges of targeted cancer prevention genetic testing and potential data re-use.

⁵² [Childhood International Protocol – Acute Myeloid Leukaemia 2022](#)

⁵³ [ICPerMed International Consortium](#)

⁵⁴ [European '1+ Million Genomes' Initiative](#).

⁵⁵ European-wide foundation to accelerate data-drive cancer research ([eosc4cancer](#))

⁵⁶ [European Partnership for Personalised Medicine](#)

⁵⁷ [European Genomic Data Infrastructure](#).

EXPECTED RESULTS AND IMPACT

As an expected outcome of the activities under the joint action, medical staff would have improved knowledge and skills in implementing genetic testing and personalised medicine in oncology.

Cancer patients accessing personalised cancer medicine services in Member States will benefit from the results of this joint action. The results of these activities are expected to bring short-term improvements in developing national programmes in personalised cancer medicine and sharing best practices among Member States and associated countries. In the mid- to long- term, this is expected to extend the coverage to a higher number of Member States and to increase the number of people who will benefit from personalised risk-assessment and targeted cancer prevention, and to reach a significant higher number of patients for cancer prevention, diagnosis, and treatment in cancer centres.

This joint action is also expected to reduce discrepancies and inequalities in Europe through a coordinated approach to current personalised cancer treatments and care.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants – CR-g-24-41 | Q4/2024 | EUR 27 900 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (joint action) in accordance with Article 195, paragraph 1, point (c), 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-24-12 Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)

POLICY CONTEXT

HERA contributes to the improvement of 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 the EU4Health 2021 work programme, HERA launched an action to assess how flexible (multi-technology) Union manufacturing and process innovation capacities can be implemented to facilitate surge manufacturing capacity and improve the Union's access to medical countermeasures. This study⁵⁸, amongst others, indicated that it is recommended to invest in mechanisms to stimulate innovation for manufacturing landscape technologies that may lead to greater flexibility in the manufacturing of medical countermeasures in the Union in the longer term.

This action is a follow-up to these recommendations, specifically focusing on medicines' production, and aims at addressing some of the challenges identified in the Commission Communication 'Addressing medicine shortages in the EU', especially to boost Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients⁵⁹ and noting that some of these critical medicines will not address cross-border health threats but rather non-communicable diseases. The EU has been confronted with critical shortages, including of critical medicines, whose absence can threaten the life of patients. Many of these medicines are off-patent.

Contextually, the scope of this action focuses on innovative manufacturing for the production of Active Pharmaceutical Ingredients (APIs), their intermediates and excipients of generic medicines. It shall address relevant technological vulnerabilities and dependencies such as nitration, cyanation, fluorination or iodination⁶⁰, and enhance the use of technologies that boost economic and supply security while possibly enabling the substitution of chemical processes by biomanufacturing processes.

This action supports the Union's pharmaceutical industry to be better able to respond to public health needs in the context of health emergencies and critical medicines' shortages. It does so by enabling the development of tools that contribute to the improvement and optimisation of manufacturing of medicines, with the objective of reducing production costs (e.g., related to labour and energy consumption), and facilitating compliance with the Union's environmental occupational and social requirements, as well as the Union's current and future needs to scale-up pharmaceutical production. This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures

⁵⁸ [A study assessing scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation of medical countermeasures for serious cross-border threats to health - Publications Office of the EU \(europa.eu\)](#)

⁵⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. [COM \(2023\)672 final](#).

⁶⁰ Commission Staff Working Document - [Vulnerabilities of the global supply chains of medicines](#)

with an all-threats approach, as well as preventing critical shortages of critical medicines, especially those in a situation of technological vulnerability with regards to the EU market. It implements the EU4Health Programme’s general objective of improving the availability, accessibility and affordability of crisis-relevant products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims at supporting improved manufacturing technologies and processes that allow for a more effective, less expensive, easier to scale-up, more sustainable and cleaner production of medicines in the Union. Innovations developed under this action should be designed to enable rapid scale-up of Union pharmaceutical production in the context of a health emergency or to prevent critical shortages of critical medicines.

This action covers activities aimed at developing support for or innovations targeting manufacturing of APIs, their intermediates and excipients, namely by developing:

- a) novel manufacturing processes and technologies, e.g., additive manufacturing, continuous manufacturing and flow chemistry, and biomanufacturing technologies;

combined or not with activities covering:

- b) novel industrial manufacturing facility designs, e.g., modular manufacturing smart manufacturing execution systems, including automation and robotics, advanced analytics, smart sensors.

Overall, the action should contribute to increasingly sophisticated enhancements to chemical and/or biological processes or decreasing the production of polluting agents. This action is limited to manufacturing technologies and processes and does not cover innovation exclusively targeting the field of quality control.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

- a) more agile, easier to scale-up, sustainable and resilient manufacturing of APIs, their intermediates and/or excipients, allowing for better capacity to respond to demand surges and prevent critical shortages of critical medicines;
- b) improved competitiveness of the Union’s manufacturing industry and support to the Union’s strategic autonomy and the Union’s industrial strategy in the field of medical countermeasures/medicines.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|------------------------------------|------------------------------------|------------------------------------|
| Call for proposals – CP-g-24-12 | Q1-Q2/2024 | EUR 17 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |

| | | |
|---|-------|---|
| Open call for proposals (action grant) | HaDEA | Economic operators and applied research stakeholders who can develop these technologies and processes |
|---|-------|---|

CP-g-24-13 Direct grants to Member States' authorities: Support to the development of sustainable, forward-looking national and Union stockpiling strategies (HERA)

POLICY CONTEXT

One of HERA's core missions is the strengthening of health security coordination within the Union during preparedness and crisis response times, and the bringing together of Member States, the industry, and the relevant stakeholders in a common effort. The main reason for HERA will doing this is to facilitate the availability of medical countermeasures - including critical medicines – in times of crisis and critical medicines.

The Commission will launch in 2024 a strategy for the Union on the stockpiling of medical countermeasures including critical medicines. Member States will need to align the national strategies developed through these direct grants with the Union's strategy, focusing e.g., on threat prioritisation and risk-based scenarios, sustainability, and deployment and distribution policies. In addition, the Commission and Member States should develop a common strategic approach to medicines stockpiling in the first half of 2024, including insights on the conditions required for stockpiling to be an appropriate and cost-effective option.⁶¹ This Joint Action will contribute to this goal and lay the foundations for a long-term stockpiling system.

Member States have different national stockpiling strategies and some of them are being developed now. There is a need to strengthen collaboration and exchange of experience to ensure sustainable stockpiling strategies at both national and Union level. This will improve preparedness and response to serious cross-border health threats. The specific needs of EU Outermost Regions due to their remoteness will be considered. 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 and has a Union added value.

This joint action supports the policy priority to respond to serious cross-border health threats including crisis and to enhance preparedness for future health emergencies with an all-health threats approach. It contributes to the achievement of 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) of Regulation (EU) 2021/522) 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 joint action is to support Member States to enhance or improve national stockpiling strategies, including for critical medicines, in an efficient and coordinated manner and to contribute to the implementation of and alignment with the Union's stockpiling strategy, in particular through:

- a) the setting up of sustainable, future-proof frameworks and strategies for Union stockpiling, deployment and distribution of medical countermeasures;
- b) the definition of the needs for stockpiling of critical medicines at the Union and national level, based on the vulnerability analysis of supply chains taking into account in particular the Union list of critical medicines;

⁶¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. [COM \(2023\) 672 final](#).

- c) the sharing of best practices on innovative stockpiling solutions and piloting of these in one or several Member States;
- d) the setting up of training and capacity building activities and networking;
- e) the development of evidence-based strategies/scenarios risk-based approach;
- f) the development of virtual stockpiling arrangements and strategies;
- g) the development or enhancement of IT solutions in synergy with EU HIP⁶² and ATHINA⁶³.

EXPECTED RESULTS AND IMPACT

The expected results and impact of the joint action are:

- a) better preparedness against serious cross-border threats to health;
- b) more sustainable stockpiles of medical countermeasures;
- c) faster distribution and deployment of medical countermeasures;
- d) better collaboration between Member States;
- e) better evidence-base for future proposals on stockpiling of medical countermeasures;
- f) incentivisation of Member States to try innovative ideas.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|-----------------------------|-----------------------------|
| Direct grants – CP-g-24-13 | Q1-Q2/2024 | EUR 10 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grants to Member States (joint action) in accordance with Article 195, paragraph 1, point (c) of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

⁶² [EU-HIP \(ssi.dk\)](https://ssi.dk)

⁶³ [Call for tenders to create IT system ATHINA – info session recording and presentations are now available! \(europa.eu\)](https://europa.eu)

CP-g-24-105 Call for proposals to support the development of novel antivirals (HERA)

POLICY CONTEXT

Viral infections represent the biggest pandemic threat, and consistently pose a substantial economic and public health burden due to their ability to cross species barriers and cause unpredictable outbreaks of viral diseases in humans. Antiviral development remains a crucial aspect of viral disease management to ensure timely and effective treatment of infected individuals and to reduce virus transmission. Further, the continuous evolution of new viral variants of COVID-19 contribute to the realisation that more tools are needed in the public health armamentarium to fight a pandemic.

The development of broad-spectrum antivirals (BSA), and BSA-containing drug combinations (BCC) can be a crucial key tool for pandemic preparedness when targeting HERA's defined viral families of concern as they target many viruses of the same family (pan-family inhibitors), or viruses belonging to different viral families (cross-family inhibitors). An important direction in the development of BSAs is to expand their antiviral activity, that is to find new targets. BSAs are a class of molecules or compounds, which inhibit replication of multiple viruses from the same or different viral families, thus reducing virus transmission from human to human, while BCCs can mitigate the development of antiviral drug resistance. Moreover, synergistic BCCs contain lower concentrations of antivirals which decrease their toxicity and reduce side effects.

This action supports the policy priority to be better prepared to respond to serious cross-border health threats. It contributes to the achievement of 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), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to diversify and advance the pipeline of BSA candidates. More specifically, it will support the development and further characterisation of broad-spectrum antivirals targeting identified HERA priority viral families, which largely can be divided among respiratory RNA viral families, such as *Paramyxo-*, *Orthomyxo* and *Coronaviridae*, as well as those targeting viral families known for causing viral haemorrhagic fever (VHF), such as *Arena-*, *Bunya-*, *Flavi-*, *Filoviridae*.

The action aims to identify a potent BSA candidate, in order to advance its clinical development. A robust pipeline should contain multiple BSA candidates for each viral family that are developed in parallel. When selecting the BSA candidate, attention will be paid to the complementarity with existing Horizon Europe projects⁶⁴.

EXPECTED RESULTS AND IMPACT

HERA's treat assessment in summer 2022 included a vulnerability analysis with regard to the availability or absence of medical countermeasures, in particular the availability of vaccines and treatment options. Given that the large majority of identified virus families lack effective vaccines and/or effective therapeutics, HERA's long-term aim is to, *inter alia*, support the creation of a diverse portfolio of BSAs and BCCs that can be further developed in clinical by

⁶⁴ E.g., HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential

identifying most promising candidates and supporting their characterisation and assessment, including through clinical trials.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|---|
| Call for proposals – CP-g-24-105 | Q1-Q2 2024 | EUR 10 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grants) | HaDEA | Private, academic and public bodies active and in the field of innovation and with adequate expertise in drug development |

CP-g-24-1 Direct grants to EU Reference Laboratories (EURLs) to support their functioning in accordance with Regulation (EU) 2022/2371 on serious cross-border threats to health.

POLICY CONTEXT

Article 15 of Regulation (EU)2022/2371 of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU⁶⁵ provides the legal basis for the setting up and operation of EU Reference Laboratories. The Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification, and reporting of diseases by Member States.

This action supports the functioning of the European Reference Laboratories (‘EURLs’), which will be nominated in 2024. The grants will cover the costs of running the EURLs.

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 the established EU reference laboratories, which solely have the required competence and responsibility to implement the action.

The policy priority of this action is strengthening the responsiveness of Member States 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 to cope with serious cross-border threats to health (Article 3, point (b), of Regulation (EU)

⁶⁵ [OJ L 314, 6.12.2022, p. 26.](#)

2021/522) through the specific objective defined in Article 4, point (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will support the costs of running the EURLs that will be designated according to Article 15 of Regulation (EU)2022/2371. These EURLs shall be responsible for coordinating the network of national reference laboratories, in particular, in the following areas:

- (a) reference diagnostics, including test protocols;
- (b) reference material resources;
- (c) external quality assessments;
- (d) scientific advice and technical assistance;
- (e) collaboration and research;
- (f) monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and
- (g) training.

The action will cover the costs of running the EURLs that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with the EU4Health Programme.

EXPECTED RESULTS AND IMPACT

This action will enable the EURLs to carry out the tasks provided by Regulation (EU) 2022/2371, and thus contribute to its implementation.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|--------------------------------------|
| Direct grants – CP-g-24-1 | Q1-Q2/2024 | EUR 7 500 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to the EU reference laboratories in accordance with Article 195, paragraph 1, point (d) of Regulation (EU, Euratom) 2018/1046 | HaDEA | Designated EU reference laboratories |

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1 MENTAL HEALTH CHALLENGES

DP-g-24-24 Direct grants to Member States' authorities: Promoting a comprehensive, prevention-oriented approach to mental health to support vulnerable groups

POLICY CONTEXT

Mental health issues affect many people across the Union. Prior to the COVID-19 pandemic, it was estimated that at least more than 84 million (1 in 6) Union citizens were affected by mental illness (2018 OECD report 'Health at a Glance'⁶⁶). This figure has increased in the context of the COVID-19 pandemic, and in the context of Russia's unjustified and unprovoked war of aggression against Ukraine and its consequences, the climate crisis, increased digitalisation, unemployment, the cost of living, and uncertainty about the future. In the spring of 2022, data indicated that on average 55% of adults could be considered at risk of depression across Member States⁶⁷. The COVID-19 pandemic has had a particularly significant impact on the mental health and well-being of vulnerable groups, such as children and young people, whose symptoms of depression, despite improvements over the course of the pandemic, have doubled in several Member States (2022 OECD report 'Health at a Glance'⁶⁸). If unrecognised and untreated, mental disorders have a significant human and financial cost, among which are negative effects on educational and employment outcomes and on affected individuals' quality of life. The direct and indirect costs of poor mental health are estimated to exceed 4% of GDP⁶⁹.

Commission President von der Leyen announced a new initiative on mental health in her 2022 State of the Union Address⁷⁰. Both the European Parliament and the Council called for action in this area as well. In addition, the EU Strategy on the rights of the child stressed the complexity of factors that influence mental health and well-being of children⁷¹ and the Commission has raised awareness about mental health in a variety of sectoral dialogues with citizens, such as the Conference on the Future of Europe⁷² in May 2022, where citizens had highlighted mental health as a major concern, as well as during the European Year of Youth⁷³.

Over the past 25 years, the Commission has initiated and supported several activities on mental health⁷⁴. These include the most recent 'Healthier Together – EU Non-Communicable Diseases Initiative'⁷⁵ that was presented in June 2022 and includes a strand on mental health and neurological disorders. It aims to support Member States in reaching the United Nations' Sustainable Development Goals⁷⁶ and the World Health Organisation's targets on non-communicable diseases⁷⁷, including mental health. Mental health is also a prominent and recurrent theme in best practice transfers across the Union supported by the Commission's

⁶⁶ Health at a Glance: Europe 2018 (OECD).

⁶⁷ Living, working and COVID-19 e-survey. [Eurofound](#).

⁶⁸ Health at a Glance: Europe 2022 (OECD)

⁶⁹ Health at a Glance: Europe 2018 (OECD) [Factsheet on Promoting Mental Health](#).

⁷⁰ [State of the Union \(europa.eu\)](#).

⁷¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU strategy on the rights of the child. [COM \(2021\)142 final](#).

⁷² [Conference on the Future of Europe](#).

⁷³ [European Year of Youth](#).

⁷⁴ European Commission – [Mental Health](#).

⁷⁵ [Healthier together – EU non-communicable diseases initiative](#).

⁷⁶ United Nations - [Sustainable Developments Goals](#).

⁷⁷ [9 global targets for noncommunicable diseases for 2025](#).

health funding programmes. Member States are already collaborating on rolling out national suicide prevention programmes and on reforming mental health services⁷⁸.

To further contribute to the improvement of mental health across the EU, the Commission launched a new approach at Union level to support and complement action at Member State and regional level. On 7 June 2023, the Commission adopted a Communication on a comprehensive approach to mental health⁷⁹ which was included in the Commission's work programme for 2023 under the priority 'promoting our European way of life'. The Communication promotes a comprehensive, prevention-oriented approach to mental health and addresses the many policies, and socio-economic, environmental, and commercial determinants that affect mental health that go beyond the health area.

The Commission's Expert Group on Public Health ('PHEG') helps to coordinate Member States' efforts, and mental health has been identified as a key area for future action. A sub-group on mental health advises the Commission in the preparation and implementation of the comprehensive approach to mental health. The sub-group provides input for the development of the approach of mental health issues, in particular with regard to national needs and objectives in the area of mental health, and the potential Union added value of the approach. The Commission intends to continue to work closely within PHEG and its sub-group on the implementation of the Communication and its flagship initiatives and actions.

The focus of the Communication is to support vulnerable and socio-economically disadvantaged population groups, such as children, young people, farmers and other people living in rural and remote areas, the elderly, migrants, refugees, displaced people from Ukraine, Roma, unemployed, LGBTQI+, prisoners and substance users. The main objective of this action is to provide effective and impactful support and guidance to these diverse groups adapted to their specific needs, as well as to ensure the adequate and effective prevention of mental health problems.

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 and has a Union added value.

This joint action supports the implementation of the Commission Communication on a comprehensive approach to mental health and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a) of Regulation (EU) 2021/522), 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 joint action is to reduce the burden of mental ill health with a specific focus on vulnerable groups through promoting good mental health, effectively preventing mental health problems and improving access to mental health treatment and services across the EU. In particular, Member States will implement the relevant flagship actions and other initiatives presented in the Commission Communication on a comprehensive approach to mental health, and other initiatives within the framework of the Healthier Together – EU NCD Initiative.

⁷⁸ JA on Implementation of Best Practices in the area of Mental Health ([JAimpleMENTAL](#))

⁷⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health. [COM \(2023\)298 final](#).

The activities will focus on the following elements:

1. promotion of good mental health and prevention of mental health problems through:
 - a. mental health literacy and awareness-raising;
 - b. knowledge-sharing and exchange programmes for health professionals;
 - c. capacity building and targeted actions creating a sustainable link between health, education and social care, linking key actors and policies and promoting a holistic and all-of-society approach to mental health;
 - d. creation of networks of institutions, patients and health professionals;
 - e. development of integrated and coherent policy approaches to key mental health challenges, such as those that the digital world poses on children (e.g., misinformation, cyberbullying, body shaming, aggressive marketing, undue access to inappropriate content);
 - f. identification and sharing of best and promising practices and approaches and implementable research results, and joint development and testing of innovative policies promising high impact.
2. early detection of and intervention in case of mental health problems through the development, piloting and implementation of a European approach to early detection and intervention to prevent mental health problems in various settings, including community-based care;
3. improved access to evidence-based and innovative, promising and personalised approaches and interventions in the management of mental health problems, including improving community-based care and approaches;
4. improved quality of life through appropriate and patient-centred follow-up care with a focus on fundamental rights and addressing stigma and discrimination.

Other activities may also focus on the implementation of the Commission Communication on a comprehensive approach to Mental health and the ‘Healthier Together’ EU NCD initiative.

Specific activities under this joint action will provide tools to support vulnerable groups and socio-economically disadvantaged groups, such as children, young people, the elderly, migrants, refugees, Roma, unemployed, LGBTQI+, substance users and prisoners, and will include:

- a) assessment of mental health needs and socio-economic risk factors of vulnerable and socio-economically disadvantaged population groups, such as children, young people, farmers and other people living in rural and remote areas, the elderly, migrants, refugees, Roma, unemployed, substance users, LGBTQI+ and prisoners;
- b) building on the existing analysis of national policies, programmes and strategies that aim to improve the mental health of the above-mentioned (not exhaustive) target groups. Member States will be able to transfer and roll-out promising and best practices and approaches, such as collected under the EU Best Practice Portal. Through this joint action, Member States’ authorities are expected to develop a template for a comprehensive policy approach to the mental health of vulnerable groups;
- c) development of a toolbox with comprehensive and tailored strategies, tools and guidance for mental health professionals, as well as other professionals (social workers, teachers, etc) that focus on each specific target group, especially for children and young people. The toolbox will be piloted in a selection of Member States and will be improved after interventions and on-the-ground experience;

- d) organisation of tailored awareness and training activities, that will help to improve the mental health of the target groups and their communities. This will specifically include breaking through stigma and reducing discrimination;
- e) set up of comprehensive and multi-sectoral networks on cooperation and information exchanges that link key sectors, such as the health, education and social sectors, that focus on mental health prevention and prevention of mental ill health of vulnerable groups;
- f) organisation of a series of workshops in each Member State, bringing together the key policy departments, to encourage a comprehensive approach to mental health of vulnerable groups at national and regional level, including the management of individuals with co-morbidities (e.g., substance use disorders, chronic diseases);
- g) where possible, involvement of representatives of each specific target group or relevant national and Union level associations in the above activities to share their expertise and help in reaching and involving the respective target groups and communities.

In carrying out this joint action, account must be taken of the outcomes of previous and ongoing actions and ensure coordination, as needed, with international organisations, such as the WHO, UNICEF, and the OECD in order to avoid duplication of activities funded under the EU4Health Programme.

Under this joint action, Member States' authorities are expected to improve and implement national policies, programmes and actions that aim to improve the mental health status of vulnerable groups as a follow-up to the mapping and capacity-building to be carried out by the WHO (DP-g-22-07.02 Addressing mental health challenges) and the OECD (DP-g-07.2.1 Collection and support for implementation of innovative best practices and research results on non-communicable diseases).

EXPECTED RESULTS AND IMPACT

The expected results of this joint action include:

- a) improved, tailored and comprehensive policy-making guidance and tools on mental health promotion and prevention of mental health problems of vulnerable and socio-economically disadvantaged groups;
- b) empowerment through improved health literacy and self-management, of vulnerable and socio-economically disadvantaged groups to take better care of their own mental health and to seek help and support;
- c) quality of life improvement of vulnerable and socio-economically disadvantaged groups due to stepped up actions, such as guidelines and awareness-raising activities, on breaking through stigma and discrimination;
- d) implementation of relevant flagship actions of the Communication of a comprehensive approach to mental health.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|-------------------------------|------------------------------------|--------------------------|
| Direct grants – DP-g-24-24 | Q1-Q2/2024 | EUR 6 000 000 |

| Procedure type | Implemented by | Type of applicants targeted |
|--|----------------|-----------------------------|
| Direct grant to Member States (one joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

DP-g-24-25 Call for proposals to support a comprehensive, prevention-oriented approach to mental health in the Union

POLICY CONTEXT

Mental ill health can have devastating effects on individuals, families, and communities, with one in every two people experiencing a mental illness in their lifetime. The 2018 OECD report 'Health at a Glance: Europe' concluded that mental health problems, such as depression, anxiety disorders and alcohol and drug use disorders, affect more than one in six people across Europe in any given year. The report estimates the total costs of mental ill health at over EUR 600 billion, which is more than 4% of European GDP.

The COVID-19 pandemic, Russia's war of aggression against Ukraine, the climate crisis, rising costs of living and uncertainty have all exacerbated the worrying trends in the mental health status of people in the Union. Although the pandemic has had an impact on nearly everyone's life, young people have been particularly hard hit.

The 2022 edition of the OECD report 'Health at a Glance: Europe' focused on how the COVID-19 pandemic has affected young people's mental and physical health. It found that about 50% of young Europeans reported unmet needs for mental healthcare in spring 2021 and again in spring 2022, and that the share of young people reporting symptoms of depression in several Member States more than doubled during the pandemic.

Mental health issues represent the largest burden of disease among young people, and mental ill health is at least as prevalent among young people as among adults⁸⁰ (OECD, 2015).

In 2021, almost 30% of contacts received by Child helpline international globally was about mental health, out of that suicidal thoughts and attempts were a major reason to call the 116 111⁸¹.

Suicide is the second leading cause of death among young people aged 15 to 19 years old⁸².

In addition, children and young people use and rely more and more on digital technologies and being online and using social media have become an integral part of their lives. As the mass availability and use of digital technologies is a relatively recent phenomenon, there is limited evidence available to date on whether digital technologies, including social media, online advertising, and gaming, cause mental health problems in children and young

⁸⁰ Fit Mind, Fit Job. (OECD)

⁸¹ Voices of Children & Young People Around the World: Global Child Helpline Data from 2021 ([Child Helpline International](#))

⁸² The State of the World's Children 2021: On My Mind – Promoting, protecting and caring for children's mental health, Regional brief: Europe, [UNICEF, 2021](#).

people. However, there is a potential link between internet use and mental health and well-being. The OECD report on “Children and young people’s mental health in the digital age”⁸³ emphasised the importance of intervening early to minimise the effects of mental illness on development, education, employment, and health.

Commission President von der Leyen⁸⁴ announced a new initiative on mental health in her State of the Union Address. Both the European Parliament and the Council called for action in this area.

In addition, mental health has been emphasised in a variety of sectoral dialogues with citizens, such as the consultations with children for the EU Strategy on the rights of the child⁸⁵, the Conference on the Future of Europe in May where European citizens highlighted mental health as a major concern, as well as in the European Year of Youth.

The Commission responded with a Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health⁸⁶, adopted on 7 June 2023.

The ‘Healthier Together’ – EU Non-Communicable Diseases Initiative’ aims to support Member States in reaching the United Nations’ Sustainable Development Goals and the WHO targets on non-communicable diseases. Mental health is addressed in this framework and is a prominent and recurrent theme in best practice roll-outs across the Union supported by the Union health programmes. Member States are already collaborating on rolling out national suicide prevention programmes and on reforming mental health services. Other best practices have been identified for wider implementation in the Member States. These include projects addressing depression, improving the mental health of children, young people and their families including those in vulnerable situations. Furthermore, the Commission supports displaced people from Ukraine who may urgently need mental health support through projects targeting this vulnerable group.

The PHEG helps to coordinate Member States’ efforts in the area of mental health, and mental health has been identified as a key area for future action. A subgroup on mental health was set up to advise the Commission in the preparation and implementation of a comprehensive approach to mental health. The Commission intends to work closely with the PHEG and its sub-group on the implementation of the Communication’s flagship actions and other initiatives.

The Commission launched the latest call for best practices in February 2022 to obtain practices under the five strands of the Healthier Together initiative. In order to identify additional best practices on mental health promotion, prevention, and early detection and intervention, the Commission has launched a round of best practices through the Best Practices Portal, which will be proposed to the Member States for wider dissemination and implementation.

This action supports the policy priority on mental health and implements the EU4Health Programme’s general objective to improve and foster health in the Union and to strengthen health systems by improving their resilience and resource efficiency (Article 3, points (a) and (d) of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), (g), and (i), of Regulation (EU) 2021/522.

⁸³ Children & Young People’s Mental Health in the Digital Age – Shaping the Future. ([OECD](#)).

⁸⁴ [State of the Union 2022 \(europa.eu\)](#).

⁸⁵ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52021DC0142>

⁸⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health. [COM \(2023\)298 final](#).

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to reduce the burden of mental ill health through promoting good mental health and effectively preventing mental health problems across the Union by supporting the efforts of the Member States in implementing the flagship actions and other initiatives of the Commission Communication on a comprehensive approach to mental health.

The activities could cover the following areas of action:

- a) promotion of good mental health and prevention of mental health problems through mental health literacy and awareness-raising, knowledge-sharing and exchange programmes for health professionals, creation of and participation in networks of institutions, patients and health professionals, identification and sharing of best and promising practices and approaches and implementable research results;
- b) support for the design of integrated and coherent health policy approaches to key mental health challenges for children, such as those posed by the digital world (e.g., misinformation, cyberbullying, body shaming, aggressive marketing, undue access to inappropriate content, addiction and concentration deficit);
- c) support for the design of comprehensive and coherent policy approaches and toolkits to address key social, environmental, commercial and behavioural factors influencing the mental health of citizens, including children and young people and their mental resilience;
- d) better and earlier detection and intervention of mental health problems through development, piloting and implementation of approaches and tools for early detection and intervention in various settings e.g., schools, workplaces, prisons and community settings;
- e) improved access to evidence-based, innovative, promising and community-level approaches and interventions in the management of mental health challenges;
- f) improved quality of life through appropriate and patient-centred follow-up care with a focus on rights and breaking through stigma and discrimination.

The activities should include an equity dimension and aim at reducing health inequalities and focus on vulnerable groups (such as children, the elderly, women in vulnerable situations and migrants and refugees, Roma people and displaced people from Ukraine) and socio-economically disadvantaged groups (such as persons with low education and incomes, or persons at unemployment risk).

This action is linked to and should support the activities under DP-g-24-24 Direct grants to Member States' authorities: Promoting a comprehensive, prevention-oriented approach to mental health to support vulnerable groups.

EXPECTED RESULTS AND IMPACT

The expected results of this action are an improved and accelerated move towards the development and implementation of a comprehensive approach to mental health, including in areas such as mental health promotion and prevention, better and earlier detection, and interventions to tackle mental health issues, access to innovative approaches to managing mental health conditions in communities, and quality of life of patients and their families/(in)formal carers in the Member States, through:

- a) collection and sharing of information, knowledge, promising and best practice approaches on a comprehensive approach to mental health under the above-mentioned areas of actions;

- b) support for national, regional and local policymakers and decision-makers in the move towards a more comprehensive approach to mental health;
- c) data identification and dissemination on the key social, environmental, commercial and behavioural factors that influence the mental health of citizens, especially children and young people;
- d) development of policy advice and of a communication toolkit on how to best reach and involve vulnerable and socio-economically disadvantaged population groups in local community settings, on mental health issues, especially depression, suicide prevention and addressing stigma and discrimination;
- e) reinforced cooperation, exchange networks and dissemination between civil society organisation to support the move towards a comprehensive approach on mental health.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|---|
| Call for proposals – DP-g-24-25 | Q1-Q2/2024 | EUR 2 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks including ERNs, civil society organisations: associations, foundations, NGOs and similar entities, established networks in the field of public health. |

2.2 NON-COMMUNICABLE AND COMMUNICABLE DISEASES

DP/CR-g-24-27 Direct grants to Member States' authorities: Health promotion and disease prevention including smoke- and aerosol- free environments

POLICY CONTEXT

In 2022, the Commission presented the 'Healthier together' – EU Non-Communicable Diseases Initiative ('EU NCD Initiative') to support Member States in identifying and implementing effective policies and actions to reduce the burden of major non-communicable diseases ('NCDs') and improve citizens' health and wellbeing.

The EU NCD Initiative covers the period 2022-2027 and includes five strands: 1) a horizontal strand on shared health determinants, focusing on population-level health promotion and disease prevention of NCDs (complementing the actions of Europe's Beating Cancer Plan); 2) diabetes; 3) cardiovascular diseases; 4) chronic respiratory diseases; and 5) mental health and neurological disorders, including dementia.

In the context of challenging demographic changes, mental health, social and long-term care services must be accessible, affordable, integrated, patient-centred community-based and user friendly. Older people should be empowered to lead a healthy and active life, manage their own physical and mental health and to increase their social interaction and reduce loneliness. Healthy longevity is a key objective across the Commission's health policies.

Financial support under the EU4Health work programmes 2022 and 2023 has been provided to support the implementation of actions identified by the Member States under the above-mentioned strands.

After the first wave of support to the Member States in the context of the EU NCD Initiative, it is important to adjust and improve the functioning of the initiative by:

- a) further refining the identification of best practices, innovative policies, and cost-effective approaches that can deliver population impact;
- b) suggesting clusters of Member States to team up and cooperate closely on the implementation of actions addressing common challenges, and
- c) addressing specific and uncovered areas to better support and target vulnerable groups in particular in the ageing population.

NCDs other than the ones covered by these strands may also be addressed through joint work and collaboration between the Member States. Such NCDs may include digestive diseases, kidney diseases, musculoskeletal disorders, substance use disorders, age-related disorders other than dementia and approaches to tackle harm due to smoking and the use of alcohol and drugs.

In the Europe's Beating Cancer Plan, the Commission announced that it would put forward actions to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2040, compared to around 25% today. The Commission intends to launch in 2024 a revision of the 2009 Council Recommendation on Smoke-free environments⁸⁷. Since 2009, there have been technological advancements and an increase in market shares of emerging tobacco products (such as e-cigarettes and heated tobacco products). In addition, the 2009 Council Recommendation on Smoke-free environments included indoor and enclosed spaces in its scope but other public spaces such as certain outdoor spaces are only covered on a case-by-case basis. With the revision, the key objective is to protect people in the Union from

⁸⁷ Council recommendation of 30 November 2009 on smoke-free environments ([2009/C 296/02](#)).

exposure to second-hand smoke and aerosols. It will address risks from emerging products or from exposure to second-hand smoke and aerosols in certain outdoor spaces.

Alcohol-related harm is a major public health concern in the EU. Under Europe's Beating Cancer Plan, the Commission will increase support for Member States and stakeholders to implement best practices and capacity-building activities to reduce harmful alcohol consumption in line with the targets of the UN Sustainable Development Goals⁸⁸.

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 and has a Union added value.

The joint action will support the policy objective of the EU NCD Initiative and Europe's Beating Cancer Plan including the creation of a Tobacco-Free Generation' and it implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, points (a)) through the specific objectives defined in Article 4, points (a), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this joint action is to reduce the burden of NCDs including cancer, and their risk factors, both at individual and population level, to promote active and healthy ageing and to support Member States in their efforts to meet the Sustainable Development Goals, in particular Goal 3, Target 3.4, as well as the NCD targets of the WHO⁸⁹.

This joint action will support the implementation of Europe's Beating Cancer Plan, in particular in terms of achieving a tobacco-free Europe through actions to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2024 compared to around 25% today. In this respect, the joint action will support the implementation of the planned Council Recommendation on Smoke- and Aerosol-free Environments and related Union legislative frameworks on tobacco control. It will contribute to protecting young people from the harmful effects of tobacco and related products.

It will support the implementation of Europe's Beating Cancer Plan with respect to reducing harmful alcohol consumption and reducing the exposure of young people to advertising of alcoholic beverages.

Specifically, the activities will include:

- a) the identification and implementation of best and promising practices, innovative policies, cost-effective approaches and research results on prevention of non-communicable diseases and risk factors common to NCDs including cancer, including in vulnerable populations; this may include NCDs other than those identified under the five strands of the 'Healthier Together' EU NCD initiative;
- b) development of integrated and coherent policy approaches to key NCD prevention and promotion challenges, such as those that affect particularly vulnerable groups, including children and young people, as well as the elderly;
- c) support on the implementation of the planned revised Council Recommendation on Smoke-free Environments and related guidelines, designing and transferring best practices and innovative approaches with the overall goal of protecting people in the

⁸⁸ This includes a target to achieve a relative reduction of at least 10% in the harmful use of alcohol by 2025.

⁸⁹ [The WHO Sustainable Development Goals \(SDG Target 3.4\).](#)

Union from exposure to second-hand smoke and aerosols, and the strengthening of coordination activities at Union level;

- d) support for the identification and piloting of best and promising practices, innovative approaches and evidence-based brief interventions that contribute to reducing alcohol consumption and related harm especially among young people and vulnerable groups, including the elderly.

Where relevant, the Member States' authorities through this joint action will address the specific needs of vulnerable population groups such as Roma populations, displaced people from Ukraine and migrants and refugees.

EXPECTED RESULTS AND IMPACT

The expected results of this joint action include:

- a) identifying and rolling-out best and promising practices for piloting or implementation of those practices through population-level interventions;
- b) designing and piloting of promising policies and supporting the replication of these best and promising practices;
- c) supporting the design and piloting of new ambitious implementation of best and promising practices and innovative approaches;
- d) developing guidelines and evidence-based recommendations for prevention and control of NCDs and their risk factors, including nutrition, physical activity, use of tobacco products and alcohol consumption;
- e) developing guidelines and evidence-based recommendations to support Member States and stakeholders in reducing the risk and exposure associated with second-hand smoke and aerosols;
- f) supporting the design and piloting of new ambitious approaches and existing best practices towards achieving smoke and aerosol-free environments leading to the collaboration among Member States and reducing existing inequalities;
- g) supporting the implementation of the planned revised Council Recommendation on Smoke-free Environments through appropriate measures at national level that support the compliance with and enforcement of smoke and aerosol-free measures.

This joint action is expected to contribute to reducing the risks from harmful exposure to second-hand smoke and aerosols in certain outdoor spaces. It is expected to reduce the burden of NCDs, including cancer, in Member States.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|------------------------------------|
| Direct grants – DP/CR -g-24-27 | Q3/2024 | EUR 16 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (one joint action) in accordance with Article | HaDEA | Member States' authorities |

| | | |
|--|--|--|
| 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | | |
|--|--|--|

DP/CR-g-24-29 Call for proposals on health promotion and prevention of non-communicable and communicable diseases, including vaccine-preventable and other cancers caused by infections, and on smoke- and aerosol-free environments

POLICY CONTEXT

In 2022, the Commission presented the ‘Healthier together’ – EU Non-Communicable Diseases Initiative (‘EU NCD Initiative’) to support Member States in identifying and implementing effective policies and actions to reduce the burden of major non-communicable diseases (‘NCDs’) and improve citizens’ health.

The EU NCD Initiative covers the period 2022-2027 and includes five strands: 1) a horizontal strand on shared health determinants, focusing on population-level health promotion and disease prevention of NCDs (complementing the actions of Europe’s Beating Cancer Plan); 2) diabetes; 3) cardiovascular diseases; 4) chronic respiratory diseases; and 5) mental health and neurological disorders, including dementia.

Financial support under the EU4Health work programmes 2022 and 2023 has been provided to support the implementation of actions identified by the Member States under the above-mentioned strands.

After the first wave of support to Member States in the context of the EU NCD Initiative, it is important to adjust and improve its functioning by further refining the identification of best practices, innovative policies, and cost-effective approaches that can deliver population impact, and addressing specific areas or areas not yet covered under the strands to better support and target vulnerable populations, including children, young people, and the elderly.

NCDs other than the ones covered by these strands may also be addressed through joint work and collaboration between the Member States. Such NCDs may include digestive diseases, kidney diseases, musculoskeletal disorders, substance use disorders, age-related disorders beyond dementia and approaches to tackle the use of tobacco products and smoking, and harm due to the use of alcohol and illicit drugs.

Since communicable diseases such as HIV/AIDS, tuberculosis and viral hepatitis continue to be an important public health challenge at Union level, they may also be addressed.

In Europe’s Beating Cancer Plan, the Commission announced that it would put forward actions to help create a ‘Tobacco-Free Generation’ where less than 5% of the population uses tobacco by 2040, compared to around 25% today. The Commission intends to launch a revision of the 2009 Council Recommendation on smoke-free environments in 2023⁹⁰. Since 2009, there have been technological advancements and an increase in market shares of emerging tobacco products (such as e-cigarettes and heated tobacco products). In addition, the 2009 Council Recommendation on smoke-free environments include indoor and enclosed spaces in its scope but other public spaces such as certain outdoor spaces were only covered on a case-by-case basis. With the revision, the key objective is to protect people in the Union from exposure to second-hand smoke and aerosols. It will also address risks from emerging products or from exposure to second-hand smoke and aerosols in certain outdoor spaces.

To increase synergies and cooperative work, relevant international organisations and stakeholders could be supported in order to address the Commission’s and Member States’ policy priorities in the area of NCDs. Civil society organisations and international

⁹⁰ Council Recommendation of 30 November 2009 on smoke-free environments (europa.eu) ([2009/C296/02](#)).

organisations, such as the WHO and the OECD, may further support the Member States in their efforts.

While cancer is usually considered within a non-communicable disease framework, a considerable number of cancers are caused by infections. Primary causes of cancers caused by infections are *Helicobacter pylori* ('*H. pylori*'), Human Papillomavirus ('HPV'), Hepatitis B and C ('HBV and HCV').

Cervical cancer is the second most common cancer among women aged 15 to 44 in the EU, with 33 000 cases and 15 000 deaths yearly. The major cause of cervical cancer is persistent infection with specific types of HPV. Further, HPV is associated with other cancers such as anogenital or oropharyngeal cancers, affecting both women and men. Viral hepatitis, according to ECDC data, is responsible for 55% of all liver cancer deaths, the number of which has increased significantly over the past decades.

While Union targets are aligned with global targets when it comes to the elimination of viral hepatitis, there is still a need for specific Union-level HPV targets.

One of the flagship initiatives of Europe's Beating Cancer Plan is to support Member States' efforts to extend routine vaccination against HPV of girls and boys to eliminate cervical cancer and other cancers caused by HPV. The objective is to vaccinate at least 90% of the Union's target population of girls and to significantly increase the vaccination of boys by 2030.

In 2023, the Commission intends to present a proposal for a Council Recommendation on vaccine-preventable cancers to support Member States in increasing HPV vaccination coverage rates in a gender-neutral perspective and to help ensure access to vaccination against HBV for all affected populations groups. The Europe's Beating Cancer Plan also commits to helping ensuring access to treatments for HCV infection, which is associated with liver cancer. Additional challenges include prevention, access to testing, linkage to care, and monitoring and quality of surveillance data.

Infections with *H. pylori* will be covered through actions supporting the implementation of the new Council Recommendation on cancer screening, which suggests test-and-treat strategies for *H. pylori* as a means for gastric cancer screening.

The 2018 Council Recommendation on strengthened cooperation against vaccine-preventable diseases⁹¹ calls for targeted outreach to vulnerable population groups. In 2020, the Commission issued a reformed EU Roma strategic framework for equality, inclusion, and participation⁹². Vaccination can contribute to reduce inequalities in health among Roma populations in the EU.

This action supports the Europe's Beating Cancer Plan, the EU Roma strategic framework; the planned Commission proposals for a Council Recommendation on vaccine-preventable cancers; and a revision of the 2009 Council Recommendation on smoke-free environments. The action also implements the EU4Health Programme's general objective to improve and foster health in the Union and to strengthen health systems by improving their resilience and resource efficiency (Article 3, points (a) and (d), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), (i), and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

⁹¹ Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases ([2018/C 466/01](#))

⁹² [The new EU Roma strategic framework for equality, inclusion and participation.](#)

The aim of this action is to contribute to reducing the burden caused by NCDs and communicable diseases and their risk factors, supporting Member States' actions. The action targets:

- a) Sub-topic (a): NCDs and their risk factors, including NCDs not covered by the strands of the 'Healthier Together' EU NCD initiative and targeting vulnerable groups of the population, such as children, young people and the elderly (e.g., auto-immune diseases, chronic kidney diseases and liver diseases, musculoskeletal disorders); and, support to the implementation of the planned Commission proposal for a revision of the 2009 Council Recommendation on smoke-free environments;
- b) Sub-topic (b): Vaccination and vaccine-preventable cancers (HPV and HBV) including implementation of the planned Council Recommendation on vaccine-preventable cancers and other cancers caused by infections (HPV, HBV and HCV);
- c) Sub-topic (c): Communicable diseases (HIV/AIDS, Tuberculosis, viral hepatitis).

Sub-topic (a) is linked to and supports the activities under DP/CR-g-24-27 Direct grants to Member States' authorities: Health promotion and disease prevention including smoke- and aerosol- free environments. Sub-topics (b) and (c) are linked to and support the activities under DP/CR-g-24-28 Direct grants to Member States' authorities: Cancers caused by infections, vaccine-preventable cancers and addressing communicable diseases (HIV/AIDS, Tuberculosis, Hepatitis).

Sub-topic (a):

Activities will aim to:

- a) support Member States' priorities and actions on addressing NCDs, in particular for vulnerable groups, such as children, young people and the elderly;
- b) build on the advice and momentum from the planned revised Council Recommendation on smoke-free environments, supporting Member States' priorities and actions to implement that recommendation.

More specific activities will include:

- a) the development and piloting of best and promising practices, innovative and cost-effective approaches and research results on prevention of NCDs and risk factors;
- b) the roll-out of already identified best practices and innovative approaches with the overall goals of protecting people in the Union from exposure to second-hand smoke and aerosols and of strengthening the coordination of activities among Member States.

Activities under sub-topic (a) should ideally complement the activities carried out under DP/CR-g-24-27 Direct grants to Member States' authorities: Health promotion and disease prevention including smoke- and aerosol- free environments.

Sub-topic (b):

Activities will aim to:

- a) Develop and pilot guidance on increasing the uptake on vaccination, in particular among vulnerable groups, on the basis of identification of best and promising practices in the field;
- b) build on the advice and momentum from the Council Recommendation on vaccine-preventable cancers, supporting Member States' priorities and actions to implement it.

More specific activities will include:

- a) targeted outreach activities to increase the uptake of vaccination among vulnerable populations, including displaced people from Ukraine (as beneficiaries of the access to healthcare provided by Council Directive 2001/55/EC of 20 July 2001 on minimum standards for giving temporary protection in the event of a mass influx of displaced persons and on measures promoting a balance of efforts between Member States in receiving such persons and bearing the consequences thereof (the ‘Temporary Protection Directive’)⁹³, when they need special actions to be integrated in the regular national health systems) and Roma in the EU;
- b) activities to contribute to the implementation of the Council Recommendation on vaccine-preventable cancers and activities to contribute to reduction of vaccine-preventable cancers and other cancers caused by infections (HPV, HBV and HCV);
- c) support for Member States in implementing actions related to the Council Recommendation on vaccine-preventable cancers, including the sharing of best practices and innovative approaches;
- d) awareness-raising and provision of information and knowledge on the impact of infections as possible causes for cancer across relevant target groups and on the importance of HPV vaccination for both girls and boys, HBV vaccination, HBV and HCV testing and treatment as well as an improved linkage to care;
- e) capacity-building for health professionals, including in terms of communication skills, and support for patient groups and vulnerable groups such as Roma, drug users, prisoners, refugees, and migrants.

Sub-topic (c):

Activities will aim to:

- a) support Member States and countries associated to the EU4Health Programme in their actions to prevent, monitor and manage communicable diseases, such as HIV/AIDS, Tuberculosis and viral hepatitis;
- b) support Member States in their actions to address stigma and discrimination.

More specific activities will include:

- a) development of best and promising practices, innovative policies, cost-effective approaches and research to prevent and monitor communicable diseases in the Union (HIV/AIDS, Tuberculosis, viral hepatitis);
- b) awareness-raising to tackle stigma and discrimination;
- c) targeted actions for vulnerable groups (e.g., drug users, migrants, people in prison)
- d) capacity-building for health professionals, including in terms of communication skills, and support for patient groups and vulnerable groups.

Activities under sub-topic (b) and (c) should ideally complement the activities carried out under DP/CR-g-24-28 Direct grants to Member States’ authorities: cancers caused by infections, vaccine-preventable cancers and addressing communicable diseases (HIV/AIDS, TB, HBV and HVC).

All activities under this call will cover the promotion of health and the prevention and management of NCDs and communicable diseases, supporting in particular vulnerable population groups, including displaced people from Ukraine (as beneficiaries of the access to healthcare provided by the Temporary Protection Directive, when they need special actions to

⁹³ [OJ L 212, 7.8.2001, p. 12.](#)

be integrated in the regular national health systems) and Roma in the EU. Activities should also include an equity dimension and aim at reducing health inequalities.

EXPECTED RESULTS AND IMPACT

Sub-topic (a):

The expected results include:

- a) identification and piloting of best and promising practices through population-level interventions;
- b) guidelines and evidence-based recommendations for prevention and control of NCDs and related risk factors;
- c) guidelines and evidence-based recommendations to support Member States and stakeholders in reducing the exposure to second-hand smoke and aerosols and the risks from emerging tobacco products;
- d) targeted interventions to promote health and prevent disease among vulnerable population groups, including children, young people and the elderly.

Sub-topic (b):

The expected results include:

- a) identification and piloting of best and promising practices through population-level interventions;
- b) concrete outputs to help increase the uptake of vaccination among vulnerable groups such as Roma, including vaccination sites/hubs, where those populations can easily get vaccinated, information material developed in collaboration with health professionals and health mediators, tools to address mis- and disinformation; and tools to strengthen the monitoring of vaccination uptake;
- c) concrete outputs to help increase the uptake of HPV and Hepatitis B vaccination among all affected population groups, including initiatives that can reduce structural barriers to vaccination, initiatives that can address vaccine hesitancy, and initiatives that can counter mis- and disinformation;
- d) concrete actions that can contribute to increased awareness and knowledge of infections as possible causes for cancer across relevant target groups.

Sub-topic (c):

The expected results include:

- a) identification and piloting of best and promising practices through population-level interventions;
- b) guidelines and evidence-based recommendations for prevention and control of communicable diseases;
- c) awareness-raising campaigns and activities targeting vulnerable groups and communities;
- d) training, upskilling and reskilling for health professionals in terms of prevention, monitoring and management of communicable diseases, focusing on vulnerable groups;
- e) activities that provide support to patient groups and organisations representing vulnerable groups.

These actions are expected to:

Sub-topic (a): contribute to reducing the burden caused by NCDs and related risk factors and communicable diseases in the Member States, and to contribute to reducing the risks from

exposure to second-hand smoke and aerosols in certain outdoor spaces and from emerging tobacco products.

Sub-topic (b): support the increase of the uptake of HPV vaccination for both girls and boys, better awareness of the risks amongst the target populations, an increased uptake of HBV vaccination among vulnerable groups, and an increased uptake of HBV and HCV testing and treatment as well as improved linkage to care.

Sub-topic (c): contribute to reducing the burden of specific communicable diseases in Member States.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|--|
| Call for Proposals – DP/CR-g-24-29 Sub-topic (a) Sub-topic (b) Sub-topic (c) | Q3/2024 | EUR 1 500 000 EUR 2 500 000 EUR 1 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks including European Reference Networks, civil society organisations: associations, foundations, NGOs and similar entities, international organisations, established networks in the field of public health, Member States’ authorities |

2.3 OPERATING GRANTS

DP-g-24-33.1/2 Call for proposals for operating grants in 2024, and call for proposals for a Framework Partnership Agreement for operating grants (2025-2026) to non-governmental organisations: financial contribution to the functioning of health non-governmental bodies implementing one or more specific objectives of Regulation (EU) 2021/522

POLICY CONTEXT

NGOs play a major role among others in providing aid at Union, national and local levels. In the field of health, and especially 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, however it is important they address funding sustainability of their operations.

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 intends to award operating grants under this work programme to eligible NGOs, and to launch a Framework Partnership Agreement ('FPA') for a duration of two years (2025-2026).

NGOs' expertise and contribution are expected to be of added value in relation to NCDs, in particular on cancer, addressing important health determinants including the harmful exposure to second-hand smoke and aerosol, ageing society, vulnerable groups and rare diseases. Poor nutrition, physical inactivity, obesity, tobacco use and the harmful use of alcohol (which are risk factors common to other chronic diseases, such as cardiovascular diseases) may also require attention.

The demographic changes, in particular the ageing 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. There is also a need 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 timeframe and specific outputs or results are intended to provide support to health NGOs that pursue one or more of the general objectives (Article 3, points (a) to (d), of Regulation (EU) 2021/522) and through the specific objectives defined in Article 4, points (a) to (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The first 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 2024 for activities including awareness raising on various health aspects, communication and dissemination, capacity building and training, expert collaboration, and networking. The second objective is to launch a Framework Partnership Agreement with eligible NGOs in view of potentially providing funding for their functioning during 2025 and 2026.

EXPECTED RESULTS AND IMPACT

Through their core operational activities, the health NGOs will deliver on increased health literacy and health promotion, capacity building and networking; and contribute to the optimisation of healthcare activities and practices by providing feedback from patients 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 schools in the Union 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. Such activities will support the implementation of the planned revised Council Recommendation on smoke-free environments and key actions in this context.

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., the WHO and other organisations).

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|---------------------------------------|
| a) Operating grants – DP-g-24-33.1 | Q4/2023 | EUR 9 000 000 |
| b) Framework Partnership Agreement - DP-g-24-33.2 | Q1/2024 | |
| Procedure type | Implemented by | Type of applicants targeted |
| Two open calls for proposals for: a) operating grants for 2024 b) a Framework Partnership Agreements for 2025-2026 | HaDEA | NGOs active in the public health area |

2.4 EU4HEALTH NATIONAL FOCAL POINTS

DP-g-24-34 Direct grants to Member States' authorities: supporting National Focal Points ('NFPs') in providing guidance, information and assistance related to the promotion and implementation of the EU4Health Programme and other relevant legislation

POLICY CONTEXT

NFP4Health is a network of national focal points established under the Third Health Programme, which provides advice to potential EU4Health funding beneficiaries at national level and enables wider participation in the EU Health Programme across countries. The NFPs provide high quality services to potential applicants based on a common sound knowledge of the rules and procedures for the implementation of the EU4Health Programme and of other relevant legislation. There is a need to maintain and increase the capacity of the public and private entities from the Member States to design proposals and create actions that deliver successfully on the health objectives for the period 2021-2027.

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 implements the EU4Health Programme's general objectives (Article 3, points (a) to (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) to (h), of Regulation (EU) 2021/522).

OBJECTIVES, SCOPE AND ACTIVITIES

The joint action aims to assist the Commission in implementing the EU4Health Programme, by promoting the EU4Health annual work programmes and its calls for applications for funding, supporting the applicants in preparing proposals, disseminating the results of the funded actions, and mediatise the impacts of the EU4Health actions in the Member States and associated countries to the EU4Health Programme.

Activities will aim to provide:

- a) information, communication and dissemination on EU4Health Programme implementation;
- b) training and education on how to facilitate the applications for funding for stakeholders in their own countries;
- c) workshops, seminars, and best practices exchanges, including discussions on possible ways forward to strengthen the NFPs' network and its visibility.

The joint action will maintain and increase the capacities of the NFPs in delivering tailored support to potential applicants implementing the EU4Health objectives.

EXPECTED RESULTS AND IMPACT

The expected results of the joint action are effective and efficient assistance for the implementation of the EU4Health Programme and delivery of tailored support to potential applicants implementing the Programme objectives reflected by a wider participation across Member State and increased NFPs' knowledge transfer capacities.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants – DP-g-24-34 | Q3/2024 | EUR 2 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (one joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

3. CANCER (CR)

CR-g-24-44 Direct grants to Member States' authorities: Paediatric palliative care

POLICY CONTEXT

The Europe's Beating Cancer Plan puts childhood cancer under the spotlight through policy actions, research efforts and funding on prevention, early detection, diagnosis, and treatment, and aims at improving the quality of life of cancer patients and survivors.

Improving communication and networking among survivors, strengthening data collection and information sharing, reducing inequalities, and improving training and knowledge in survivorship have been identified as potential areas of action. This action can be promoted via sharing of previous experiences of members of cancer survivors organisations as well as via the consultation with stakeholders.

There is evidence of inequalities in Europe between and within countries in relation to the availability of palliative care for children affected by cancer. Major barriers might be found in 1) the lack of resources, 2) the lack of paediatric palliative care programmes and workforce at the health systems level, 3) difficulties in integrating palliative care into existing paediatric oncology care models, and 4) the lack of knowledge about paediatric palliative care.

Three main types of services provide palliative care specifically dedicated for children with life-limiting conditions in Europe: (1) inpatient hospices (stand-alone facilities), (2) hospitals and (3) home care programmes. Most of the Member States offer one or two types of services and only few countries provide all three types of services. To sum up, across Europe and beyond, different models and strategies for palliative care for children with cancer exist, including early integration of palliative care for children and their families at the moment of the diagnosis, and home care.

In this sense, it is necessary to support public health authorities in terms of a coordinated, harmonised, and comprehensive approach by strengthening their capacity for paediatric palliative care. In addition, specific education on paediatric palliative care is key to strengthening the health workforce capacity to provide care to neonates, children and adolescents and to support their families.

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 and has a Union added value.

This joint action stems from the Europe's Beating Cancer Plan and implements the EU4Health Programme's general objective to improve and foster health in the Union to reduce the burden of communicable and non-communicable diseases by supporting health promotion and disease prevention (Article 3, point (a), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, point (a), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objectives of this action are to:

- a) increase knowledge of where the gaps are in paediatric palliative care services and share the best models and practices to reduce inequalities;

- b) improve information resources available to parents, and improve support for parents and children with a serious health condition, for workforce in hospitals and for other palliative care providers, including also training needs;
- c) enhance assistance for children affected by cancer by coordinating the approach at Union level and in countries associated to the EU4Health Programme;
- d) ensure that the actions taken focus on upscaling the access to paediatric palliative care for those in need within Member States and develop stronger collaborations and exchange of best practices within the Union and with countries associated to the EU4Health Programme that have a strong interest in improving paediatric palliative care.

This joint action should contribute to the implementation of the tenth flagship of the Europe's Beating Cancer Plan: the 'Helping Children with Cancer Initiative' aiming to ensure that children with cancer have access to rapid and optimal detection, diagnosis, treatment and care. The 'Helping Children with Cancer' flagship is an 'umbrella initiative' that supports actions targeted to the development of tools to share best practices, to train workforce on childhood cancer, and to allow a better access to diagnosis and treatment. In carrying out the joint action, use will be made of the guidelines, protocols, and best practices, developed within Member States, and of the experiences from the ERNs, and in particular of those 4 ERNs which address cancer (GENTURIS, PaedCan, EURACAN, EuroBloodNet), especially the one (PaedCan) on childhood cancer.

The activities carried out under this joint action should include at least:

- a) preparing the mapping in the Union and in countries associated to the EU4Health Programme of existing palliative care strategies, legislation and plans in paediatric oncology; identifying any gaps and the needs to be addressed;
- b) identifying best practices and recommendations, the models can be applied throughout different Member States and countries associated to the EU4Health Programme;
- c) extending paediatric palliative care best practices to already existing structures in Member States, including countries associated to the EU4Health Programme in order to improve the quality of patient care;
- d) improving access of paediatric patients to effective palliative care in Member States that have limited resources e.g., Eastern European countries;
- e) developing structures in Member States that are lacking paediatric palliative care frameworks to offer better quality palliative care for paediatric patients (for example, facilitate resources for inpatient hospices, home care programmes etc.);
- f) providing specific education and training; recognising medical and, nursing specialities in paediatric palliative care for healthcare workforce;
- g) improving networking of palliative care providers with multidisciplinary professionals in order to provide a holistic care to patients;
- h) providing programmes for psychological and well-being support for patients, parents, family members and carers;
- i) providing and improving telemedicine consultations and health digital support for home palliative care in the paediatric domain;

- j) developing research activities at national, European and international level to improve the collaboration between different institutions, organisations that are studying paediatric palliative care, including paediatric medicine for pain management;
- k) developing information and dissemination campaigns of paediatric palliative care for healthcare workers and general public.

This shall include building on existing Union structures and models including existing European Reference Networks.

EXPECTED RESULTS AND IMPACT

The joint action is expected to result in an improvement of the availability and quality of palliative care across Europe with the overall goal to achieving a more equitable coverage of palliative paediatric care across Europe.

In the short term, the action will focus on the transfer of good models, strategies and best practices from regions and countries which have in place effective plans and strategies for regions and countries, including both Member States and countries associated to the EU4Health Programme where paediatric palliative care services are limited or fragmented.

In the medium term, the action will support improving existing palliative care strategies in Member States and countries associated to the EU4Health Programme and will increase the quality of available palliative care services for paediatric patients and their family.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|------------------------------------|
| Direct grants - CR-g-24-44 | Q2-Q3/2024 | EUR 14 500 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States' (one joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

CR-g-24-37 Call for proposals to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes

POLICY CONTEXT

The European Cancer Imaging Initiative⁹⁴ is a Flagship of the Europe's Beating Cancer Plan. The aim of the initiative is to foster innovation and deployment of digital technologies in cancer treatment and care, to achieve more precise and faster clinical decision-making, diagnostics,

⁹⁴ [European Cancer Imaging Initiative | Shaping Europe's digital future \(europa.eu\)](https://european-cancer-imaging-initiative.eu/).

treatments and predictive medicine for cancer patients. In the framework of the initiative, a pan-European federated infrastructure of de-identified, real-world imaging data of cancer patients will be created. The data will come from Union-level and national initiatives, hospital networks, and research repositories and infrastructures. The infrastructure will be used by clinicians, researchers, and innovators to develop and test AI algorithms and AI-based solutions for more precise and faster clinical decision-making, diagnostics, treatments and predictive medicine in cancer care.

The Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC⁹⁵ extends the recommended screening to new cancer types and sets ambitious targets for cancer screening in Europe. In its Recommendation, the Council asks Member States to collect, manage and evaluate the data, and to consider, where appropriate, making the data available for cancer research, including implementation research and for the development of improved technological possibilities for early cancer diagnosis and prevention, in full compliance with applicable data protection legislation. The implementation of this Council Recommendation is being supported by EU4Health funded projects such as SOLACE (Strengthening the screening of Lung Cancer in Europe)⁹⁶, and Direct grants to Member States' authorities: Implementation of cancer screening programmes (CR-g-23-38) under the 2023 EU4Health annual work programme⁹⁷.

It is important to link the two actions of the Europe's Beating Cancer Plan, in particular since the AI-based technological solutions for the imaging data can support Member States in the implementation of screening programmes. On the other hand, imaging data representative of the European population is necessary to develop transferable AI-based solutions that can cover different European regions and benefit the European population.

The proposed European Health Data Space ('EHDS')⁹⁸ aims at advancing the use and reuse of health data for healthcare provision, research, innovation, policy-making and regulatory activities. The health data access bodies that would be set up in the context of the EHDS would, once the EHDS Regulation has been adopted, facilitate the secondary uses of health data. Secondary use means further use beyond healthcare provision, which can help, for example, advance medical technologies for cancer with the support of new AI models.

This action will support the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522.

This action will also support the implementation of the proposed EHDS Regulation and implement the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d) of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

⁹⁵ [OJ C 473, 13.12.2022, p. 1.](#)

⁹⁶ [SOLACE \(europa.eu\)](#)

⁹⁷ [EU4Health 2023 WP \(CR-g-23-38\).](#)

⁹⁸ [Proposal for a Regulation of the European Parliament and of the Council of the European Health Data Space. COM \(2022\)197 final.](#)

The action will provide enabling support for cancer imaging data providers, to contribute to and benefit from the European Cancer Imaging Initiative.

The action will improve readiness of national, regional or local imaging data repositories to connect and make available their data via the European infrastructure of cancer images data established under the DIGITAL programme (EUCAIM project⁹⁹) and to use this infrastructure for data enrichment and insights by accessing the nodes, tools and methodologies offered by EUCAIM.

This action is relevant for the proposed European Health Data Space. In order to contribute to the planned EHDS, this action will seek alignment with the relevant EHDS infrastructures (MyHealth@EU and HealthData@EU). Where applicable, it will link cancer imaging databases with the relevant bodies and infrastructures in the proposed EHDS, particularly health data access bodies and HealthData@EU.

This action will also explore ways to leverage on the EHDS interoperability specifications for the European Electronic Health Record exchange Format, including relevant eHealth Network guidelines, as well as minimum specifications for datasets to be used for research and innovation.

The following activities should be addressed to:

- a) increase the geographical coverage of the European Cancer Imaging Initiative;
- b) increase the availability of cancer imaging data representative of the European population for the development of trustworthy and scalable AI-based solutions for cancer screening and care in the area of breast, lung and prostate cancers in the context of the European Cancer Imaging Initiative;
- c) increase the availability of cancer imaging data made available for research and innovation in the context of the proposed European Health Data Space;
- d) contribute to the alignment with the relevant bodies and infrastructures of the proposed European Health Data Space, particularly health data access bodies, HealthData@EU and MyHealth@EU;
- e) provide targeted and onsite support in adopting the guidelines on the best data warehouse architectures, creating the data warehouses necessary for making the data available for secondary use, establishing internal processes, training and addressing the legal issues in alignment and complementarity with the activities under the EUCAIM project and in alignment with the proposed European Health Data Space rules and infrastructures;
- f) provide support measures for quality-control, annotation and extraction of the data from the Electronic Health Records (EHRs) to the data warehouse, supporting the uptake of the European Electronic Health Record exchange Format;
- g) use and contribute to applicable minimum specifications for datasets related to cancer imaging, including data elements, controlled vocabularies, quality requirements, in alignment with the proposed European Health Data Space Regulation;
- h) increase the awareness, in cancer-related use cases, of medical images and reports specifications of the European Electronic Health Record exchange Format;
- i) provide activities to facilitate the adoption of AI-based technologies based on imaging data in the daily practice of clinical centres to support cancer screening, detection and treatment;

⁹⁹ European Institute for Biomedical Imaging Research ([EUCAIM | EIBIR](#)).

- j) increase access to and uptake of innovative AI-based solutions based on imaging data for cancer detection and treatment;
- k) empower patients to donate their health data through data altruism, including incentives, methods and tools for data altruism targeted at empowering patients in relation to donating their health data, in particular imaging data;
- l) increase resource efficiency of national healthcare providers through the deployment of AI-based technological solutions;
- m) contribute to other relevant actions under the Europe’s Beating Cancer Plan and Cancer Mission, involving patient organisations and establishing links with data altruism organisations and regional, national or European initiatives on health data reuse for research and innovation.

EXPECTED RESULTS AND IMPACT

The action will support hospitals and other imaging repositories, for example those involved in conducting cancer screening, in creating enabling conditions for becoming a node in the European federated infrastructure of cancer imaging data. Short-term improvements include strengthening the collaboration between national and regional screening programmes for breast, lung and prostate cancers, with the European Cancer Imaging Infrastructure in particular regarding the management of the screening data and opportunistic screening (as opposed to organised, population-based screening programmes) and with the relevant infrastructures of the proposed European Health Data Space, such as HealthData@EU. The project beneficiaries are expected to represent a wide range of relevant stakeholders such as researchers, NGOs, experts, Member States institutions and industry.

In the mid-term, this action is expected to increase the geographical reach of the European Cancer Imaging Initiative. It will also contribute to the alignment of the European Cancer Imaging Infrastructure with the proposed EHDS infrastructures and processes.

Close collaboration of projects participants is expected with the European Cancer Imaging Initiative, in particular the EUCAIM project, and with relevant stakeholders involved in the implementation of the proposed EHDS regulatory framework. Links should be established with EU4Health actions on screening, Comprehensive Cancer Centres in Member States and other relevant actions under the Europe’s Beating Cancer Plan and Cancer Mission, as well as with other relevant actions concerning the proposed EHDS. The action shall contribute to other relevant actions under the Europe’s Beating Cancer Plan and the Cancer Mission.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|---|
| Call for Proposals – CR-g-24-37 | Q1/2024 | EUR 8 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert |

| | | |
|--|--|--|
| | | networks including ERNs, civil society organisations: associations, foundations, NGOs and similar entities, private entities (for profit/not for profit), Member States' authorities |
|--|--|--|

CR-g-24-39 Call for proposals to increase health literacy on cancer prevention and care

POLICY CONTEXT

Improving access to and understanding of risk factors to health risks and of health determinants is vital to improve health outcomes, especially for complex diseases like cancer. Europe's Beating Cancer Plan includes actions to give people the information and tools they need to make healthier choices and to promote cooperation between health and social services and the community.

Health literacy is an essential part of quality, patient-centred care. Cancer health literacy poses a particular set of challenges compared to other types of health literacy, as patient decisions and treatment schedules are often complex, and timely decision-making can be critical. Clear, efficient communication is vital to help patients understand and make decisions about their treatment and to manage the side-effects of cancer treatment.

One of the policy objectives of Europe's Beating Cancer Plan is to launch a project on 'Health Literacy for Cancer Prevention and Care' to develop and share best practice to strengthen health literacy on cancer prevention and care programmes, with a focus on disadvantaged groups, including refugees and displaced persons from Ukraine. In addition to influencing prevention, screening and treatment decisions, low health literacy can negatively affect the use of palliative care and end-of-life services. This project is expected to establish the necessary links and contribute to the creation of the future European Cancer Patient Digital Centre¹⁰⁰, which is an initiative launched under the EU Cancer Mission.

Using digital tools and solutions in cancer prevention and care can contribute to improving cancer health literacy, especially in for disadvantaged groups and in disadvantage regions, increasing patient sovereignty and contributing to tackling inequalities. For instance, providing reliable, easy-to understand digital or electronic health information and patient resources or digital medical advice to persons in structurally weak regions with less access to medical care.

This action supports the implementation of the Europe's Beating Cancer Plan objective to launch a project on 'Health Literacy for Cancer Prevention and Care' and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, point (a), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The main objective of this action is to support health literacy for cancer prevention and care, to improve health literacy and to focus on reducing inequalities in cancer prevention and care.

The action will include activities to:

¹⁰⁰ eTendering - [Study providing an operational concept for a European Cancer Digital. Centre](#)

- a) improve health literacy of citizens, of patients of all ages, as well as of healthcare professionals;
- b) improve health literacy of citizens on cancer prevention and provide them access to adequate and reliable health information in order to empower them to make informed decisions supporting healthy lifestyles and improving health for all citizens of all ages;
- c) improve health literacy of patients by providing adequate, reliable, and timely information on their diagnosis and treatment to achieve their disease understanding and active involvement in the treatment; improve health literacy in palliative care;
- d) improve health literacy education of health professionals:
 - a. raising awareness of the impact low health literacy can have on people at risk of cancer and cancer patients;
 - b. providing healthcare professionals with health-literacy-friendly communication techniques to support their interactions with cancer patients.

Provide access to reliable, accurate and easy-to understand information to:

- a) improve access to reliable, accurate cancer information in different languages, with attention to varying digital and literacy skills and accessibility;
- b) improve access to reliable, accurate information on the internet, to combat misinformation available online / in social media to educate and protect citizens and patients from misinformation on the Internet and social media;
- c) support cancer literacy in relation to emotional impact and psychosocial distress of cancer patients;
- d) build a 'Virtual library' on communication in cancer prevention and care;
- e) reduce medical jargon and improve education using plain language, easy-to-understand written materials, including visuals to provide more culturally and linguistically appropriate health education and enhanced web-based information.

Promote health literacy, exchange of information and best practices to:

- a) introduce a cancer health literacy day to raise awareness and promote its importance;
- b) support the generation and dissemination of evidence and good practices, including at population level;
- c) gather lessons learned to enhance health literacy in general, for example, through the establishment of cancer literacy projects;
- d) get an overview of health literacy programmes developed within healthcare systems and in the community;
- e) reflect on the role of health literacy in cancer prevention and care, potential gaps, and recommendations for action;
- f) promote collaboration and exchange of information, innovations and experience on cancer health literacy between Member States and other relevant stakeholders.

EXPECTED RESULTS AND IMPACT

The expected results include:

- a) guidelines, recommendations, lessons learned, best practices on how to increase health literacy in cancer prevention and care;
- b) information materials (e.g., manuals for patients, leaflets, websites, videos) to citizens/patients of all ages (focusing on vulnerable populations) and healthcare specialists;
- c) mapping of sources providing reliable, accurate information on the internet, in easy-to understand language;
- d) training course for healthcare specialists.

This action will increase health literacy of the general population, patients, and healthcare specialists in the area of cancer prevention and care. The action will enable citizens to take informed decisions as regards prevention and screening. It will help patients to take active involvement in treatment and will help healthcare specialists to transmit the information in an easy-to understand way.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|--|
| Call for proposals - CR-g-24-39 | Q1/2024 | EUR 5 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open calls for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations: associations, foundations, NGOs, enterprises (incl. social enterprises and not for profit) in the field of public health, private entities, social media outlets press and journalist association, Member States' authorities |

CR-g-24-40 Direct grants to Member States' authorities: to support quality improvement of cancer registry data feeding the European Cancer Information System

POLICY CONTEXT

Making the most of data and digitalisation in cancer prevention and care is one of the commitments of Europe's Beating Cancer Plan. The Plan aims to help researchers exchange findings across Member States, and to improve access to crucial health data for medical staff and hospitals. The first flagship initiative of the Cancer Plan to be launched was the European Knowledge Centre on Cancer, in June 2021, which hosts among others the European Cancer Information System ('ECIS').

ECIS is the reference point for aggregated data to feed cancer policies and for research, allowing the monitoring and comparison of cancer trends across European regions, including also in the future to contribute to the monitoring of the implementation of the 2022 Council Recommendation on cancer screening. It is fed by European cancer registries' data. ECIS future developments include incorporating up-to date aggregated data on survival and prevalence, as well as exploiting treatment and cancer stage information.

In this context, support is needed for the cancer registries to improve timeliness, accuracy and completeness of the data, and to meet the required standard data quality criteria for ECIS. Moreover, support is needed to validate and process the data collected via data calls to European registries and derive survival and prevalence statistics to complement available cancer figures already included in ECIS. These should be aligned with the current ECIS settings for incidence and mortality figures in terms of geographical detail, cancer site definition, age range availability and timeliness.

Interoperability of health data represents one of the major obstacles for increasing its use. The proposed European Health Data Space ('EHDS') aims at advancing the use and reuse of health data for healthcare provision, research, innovation, policy-making and regulatory activities. eHealth Network guidelines and the outputs of joint action TEHDAS, among other initiatives in the context of the planned EHDS, are relevant for supporting the improvement of registry data quality that will feed the ECIS. Such registry data could have further use in the EHDS with such access enabled by health data access bodies.

The action further aligns with the European Cancer Inequalities Registry, which is another flagship initiative of the Cancer Plan, and which compares aggregated data across several inequality dimensions, such as country, sex or income. Better and timelier data from the registries will also feed into the data tool 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 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 and has a Union added value.

This joint action stems from the Europe's Beating Cancer Plan and its first flagship initiative to launch the European Knowledge Centre on Cancer which hosts among others the ECIS and it implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a), of Regulation 2021/522), through the specific objectives defined in Article 4, points (a) and (f), of Regulation (EU) 2021/522.

This action will also support the implementation of the proposed EHDS, and it implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)

of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

Main objective 1: quality improvement of cancer registry data

- a) compliance with Union data quality standards, including (re)codification of cancer registries' variables according to the European Network of Cancer Registries ('ENCR') guidelines, JRC-ENCR protocol requirements and minimum standards on data quality indicators;
- b) improving completeness of cancer records, increasing access to primary data sources and standardisation and harmonisation of data collection and extraction processes whenever not yet available (hospital discharge records, pathological reports, etc.); possibly taking advantage of the European Electronic Health Record exchange Format;
- c) improving completeness of cancer variables, accessing additional data sources to retrieve missing information (i.e., clinical variables such as treatment, stage, etc.) possibly taking advantage of the European Electronic Health Record exchange Format;
- d) aligning access and exchange of electronic health data from cancer registry data with the relevant frameworks envisaged in the proposed EHDS, and particularly health data access bodies;
- e) providing the geographical references for cancer records according to the Nomenclature of Territorial Units for Statistics ('NUTS') – for the situations (areas/years) classified according to a different administrative division, i.e., LAU (local administrative unit) or others;
- f) exploring the use of the data quality and utility label developed in the context of the proposed EHDS;
- g) aligning cancer registries' specifications for datasets with the proposed EHDS Regulation, including, at least, data elements, controlled vocabularies, quality requirements;
- h) exploring the interplay and alignment between the ECIS and the relevant EHDS infrastructures;
- i) linking cancer registries and screening registries data, using Union tools and guidelines supporting the harmonisation of screening information at Union level building on the outcomes of the CanScreen ECIS project;
- j) establishing a sustainable mechanism for regular provision of aggregated screening data and information to ECIS;
- k) setting up at the regional or national registry level the necessary infrastructure (administrative, technical equipment, adherence to metadata standards) to allow for the implementation of a decentralised model for contribution to the ECIS.

Main objective 2: Improving survival and prevalence indicators in the ECIS

The second main objective of the action is to improve survival and prevalence indicators in ECIS by:

- a) building on the already available mechanism in Member States to feed the ECIS with aggregated data held by cancer registries. This part of the action should consist in validating and processing data collected via data calls to European registries and deriving up-to-date survival and prevalence indicators in alignment with the current ECIS settings for incidence and mortality figures, in terms of geographical detail, cancer sites definition, age range availability and timeliness;

- b) including pseudonymised and anonymized data sets, subject to data availability, computing survival and prevalence indicators for countries associated to the EU4Health Programme.

EXPECTED RESULTS AND IMPACT

The expected results are:

- a) the improvement of timeliness, accuracy and completeness of cancer registries' data feeding the ECIS for increased efficiency of the built infrastructure and mechanism to provide an exhaustive and comprehensive picture of the burden of cancer in European Union;
- b) an increased availability of high-quality data originating from cancer registries for further use in the EHDS;
- c) the improvement and expansion of the ECIS to include additional dimensions of cancer statistics complementing aggregated data on incidence and mortality;
- d) the development of the ECIS to become the European reference to monitor cancer burden and trends over time.

The Union will benefit from indicators which will be used to fine-tune cancer treatment programmes and approaches in cancer care according to high Union standards.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants - CR-g-24-40 | Q2-Q3/2024 | EUR 13 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (one joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

CR-g-24-42 Call for proposals on radiation safety and quality of computed tomography imaging of children, adolescents and young adults

POLICY CONTEXT

Nuclear and radiation science and technologies play an important role and provide a wide range of benefits to Union citizens in many areas, in particular in medicine. At the same time, medical procedures remain by far the largest artificial source of exposure to ionising radiation of Union citizens, including European children, adolescents, and young adults. If they are conducted appropriately, these technologies offer nevertheless medical benefits that far outweigh the risks associated with radiation exposure.

Euratom legislation¹⁰¹ on radiation protection in medicine requires that medical ionising radiation procedures are used only when appropriate and clinically justified, and with the minimum clinically needed radiation dose. It also includes requirements with respect to staff, procedures and equipment in use, and mandates a number of quality and safety tools, with particular attention to applications involving childhood exposures.

The recent EU-funded EPI-CT cohort study¹⁰² shows an excess of relative risk of brain cancer after radiation exposure from computed tomography ('CT') exams of children (0-18 years) adolescents and young adults (19-25 years). These conclusions emphasise careful justification of paediatric CT exams and use of doses as low as reasonably possible.

This action is part of the Strategic Agenda for Medical Ionising Radiation Applications ('SAMIRA') Action Plan¹⁰³ and supports the Europe's Beating Cancer Plan objective to ensure high standards in cancer care. It implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (c), (g) and (h) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the action is to enhance the quality and radiation safety of medical applications of ionising radiation in children, adolescents and young adults. Actions taken should in particular focus on computed tomography procedures in children and young adults and aim to reduce the associated risk of adverse secondary effects, such as brain and other types of cancer.

This action should cover in priority head CT exams in children, adolescents and young adults. It can be extended to other body regions, as well as other imaging modalities involving ionising radiation, if there is a frequent clinical indication for paediatric imaging and improved justification and optimisation is considered achievable. This action could include conventional and interventional radiology, CT and nuclear medicine and could also include imaging procedures performed as part of radiotherapy treatments.

¹⁰¹ 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 ([OJ L 13, 17.1.2014, p. 1](#)).

¹⁰² Hauptmann M, Byrnes G, Cardis E et. al. Brain cancer after radiation exposure from CT examinations of children and young adults: results from the EPI-CT cohort study, *Lancet Oncol* 2023; 24: 45–53.

¹⁰³ Commission Staff Working Document on a Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA), [SWD \(2021\) 14 final](#).

The activities carried out in this action should include the following:

- a) review of referral guidelines for imaging, clinical guidelines, and clinical decision support systems in use in Member States for justification of head CT in children, adolescents and young adults and recommendations for improvement of these guidelines to the relevant actors;
- b) review of the equipment base and the access to dedicated paediatric imaging in Member States for head imaging in children, adolescents and young adults and recommendations for improvement of the equipment base to the relevant actors;
- c) development of guidance, protocols and tools for optimisation of paediatric head CT exams, for the CT devices and the clinical indications that are the most used in Europe;
- d) the organisation of information and dissemination campaigns concerning recommendations, guidance, protocols and tools for justification and optimisation of paediatric imaging among the concerned hospitals and medical centres in all Member States;
- e) development of education and training curricula, material, and tools on radiation protection of paediatric CT patients, for the applicable professional groups;
- f) the organisation of a training of radiologists, radiographers, medical physicists, and radiology nurses in practical approaches to radiation protection of paediatric CT patients;
- g) the organisation of information campaigns about the benefits, risks and radiation safety of CT imaging in paediatric, adolescent and young adult patients, targeted at parents and young adults.

EXPECTED RESULTS AND IMPACT

As an expected outcome of the activities and in line with the SAMIRA objective to ensure that applications of ionising radiation in Member States operate in line with high standards for quality and safety, medical staff should have improved tools to ensure justification and optimisation of medical procedures involving ionising radiation in children and young adults. This should take various forms of technical/practical tools, like improved imaging referral and clinical guidelines, guidance, protocols and tools for specific exams and equipment, education and training curricula and material. Trainings for the hospital staff and information campaigns should also be organised.

This will benefit paediatric, adolescents, and young adult patients, and parents and young adults accessing imaging services in Member States. The actions are expected to bring short-term improvements in radiation safety and quality of CT imaging in children and young patients and reduction of avoidable exposure to ionising radiation. In the mid- to long- term, this is expected to translate into reduced avoidable secondary effects, such as brain cancer linked to head CT exams.

The outcomes of these activities should also reduce discrepancies in Europe to current radiation technology in medical applications through a coordinated approach.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|------------------------------------|------------------------------------|--------------------------|
| Call for proposals - CR-g-24-42 | Q2/2024 | EUR 3 000 000 |

| Procedure type | Implemented by | Type of applicants targeted |
|---|-----------------------|--|
| Open calls for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations, associations, foundations, NGOs, enterprises (incl. social enterprises and not for profit) in the field of public health; private entities (for profit/not for profit); international organisations; Member States' authorities |

CR-g-24-43 Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme

POLICY CONTEXT

One of the 10 flagship initiatives of Europe's Beating Cancer Plan is to put childhood cancer under the spotlight. This can be realised through a stronger multidisciplinary cancer workforce. High-quality cancer care depends on a high-quality workforce.

There is still a great lack of adequate psychosocial care in the field of childhood cancer in numerous European countries, including countries associated to the EU4Health Programme. Children, adolescents, and young adults with cancer require comprehensive psychosocial care, however the provisions of this care seem to vary significantly across European countries and also within countries. By 2030, it is estimated that there will be around 750 000 paediatric cancer survivors in Europe.

In developed countries, in oncology clinics and departments, a clinical onco-psychologist is one of the main actors. Together with the attending oncologist, he/she conducts therapy and orients patients towards a positive perception of the prescribed treatment.

Psycho-oncological care should be provided at all stages of the disease: during intensive treatment, rehabilitation, and, if possible, during the process of dying (terminal stage). The mental state of patients with oncological pathology is characterized by a decrease in mood and activity, combined with anxiety associated with low control over the disease, its recurrent nature, and uncertainty of the prognosis. Improving the quality of life of a cancer patient is an integral part of the entire process of fighting the disease. Psycho-oncology is a relatively new branch of medical psychology. Its aim is to improve the quality of life of cancer patients. Grappling with the disease can be greatly influenced by the psychological state of the patient. Daily meetings between the patient and the psycho-oncologist, who support the patients at every stage of their treatment, have a leading place. In addition to the patients, the specialists also work with their families, as well as with the medical teams (paediatric oncologist, physiotherapist, nurse etc.).

This action supports the implementation of the Europe's Beating Cancer Plan to support childhood cancer and implements the EU4Health Programme's general objectives to strengthen health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, point(g), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The main objective of this action is to create a service in paediatric oncology clinics that will support children and their families during cancer treatment, by providing the necessary psychological and social support to infants, children, adolescents, and young adults from 0 months to 24 years old.

The aim of this action is to develop:

- a) an organisation and teams in onco-paediatric clinics;
- b) tools and training sessions as a social service for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics as part of a patient treatment plan;

- c) a mapping of psychosocial services from the perspective of psychosocial health professionals working in treatment centres across Europe. In some Member States, psychosocial support is provided by the public healthcare system and in some others by cancer organisations.

The action could support the identification of the different capabilities available across Europe and build the foundation to regularly identify gaps and needs to be addressed at national and regional level across Europe. This process will be focused on quality of life and well-being of children, adolescents, and young adults, their families, siblings, and relatives, including mental, psychosocial and nutritional support, together with clinical oncology, surgery and radiology specialities, including their nursing services.

Support activities include psychological support; meeting daily activity needs; return to normal social contacts and activities inclusion, by developing communication and group work skills; utilization of free time through games; entertainment, etc.

All activities are tailored to the general state of health of the children and young people with oncological diseases. Special attention is directed to the needs and their skills, according to their age and physical capabilities.

EXPECTED RESULTS AND IMPACT

The action will contribute to the development of a social service for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics across the Union and countries associated to the EU4Health Programme. This action will identify the need to establish a Europe-wide psychosocial care standard in order to ensure high-quality psychosocial care throughout the whole paediatric oncological treatment trajectory, including the transition from the paediatric to the adult care, and to eliminate inequalities in access to care.

This action will help Member States and countries associated to the EU4Health Programme to improve cooperation among their cancer services, by addressing skill gaps and better equipping the health workforce with personnel trained in cancer care.

This action will help with overcoming the consequences of the drastic separation from the usual environment, to deal with physical discomfort, late effects of treatment, low self-esteem, and lack of self-confidence.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|--|
| Call for proposals – CR-g-24-43 | Q1/2024 | EUR 7 400 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open calls for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations, associations, |

| | | |
|--|--|--|
| | | foundations, NGOs, private entities (for profit/not for profit); international organisations, Member States' authorities, municipalities and national authorities in the health domain |
|--|--|--|

CR-g-24-45 Call for proposals on EU Network of Youth Cancer Survivors

POLICY CONTEXT

Europe's Beating Cancer Plan commits to putting childhood cancer under the spotlight and to improving the quality of life for cancer survivors. As part of the 'Helping Children with Cancer Initiative' an EU Network of Youth Cancer Survivors was launched. This EU Network is aiming to improve the quality of life of young cancer survivors through improved social networking, using the platform created by the project to strengthen the links between patients and their carers, cancer survivors, as well as social and healthcare professionals across the Union and countries associated to the EU4Health Programme.

Young individuals nominated as network representatives are to lead a collaborative approach involving diverse stakeholders to identify targeted actions and initiatives to be promoted via the network and the platform. Following a call for proposals for the EU Network under the EU4Health work programme 2021, the project EU Network of Youth Cancer Survivors ('EU-CAYAS-NET') was launched in September 2022 and is expected to be finalised in August 2024. The project OACCUs was launched in June 2022 and expected to be finalised in June 2024.

The EU-CAYAS-NET improves the quality of life of childhood, adolescent and young adult cancer survivors through improved social networking and the use of a platform to improve the links amongst patients, health professionals and other stakeholders. The network is focused on three topics which young cancer survivors have identified as a priority: quality of life; adolescent and young adult care; equality, diversity and inclusion. The network organises activities that are promoted through its platform, such as peer visits, meetings, trainings, virtual co-working, webinars, international events or policy recommendations.

OACCUs is a network promoting a healthy lifestyle through a) outdoor sports and exercise, b) psychoeducation, c) healthy nutrition, d) healthy environment (respectively sustainable lifestyle), which is achieved through interaction and exchange with peers, with people with a similar disease history, with their friends with healthcare organisations (universities, organisations for young cancer survivors, NGOs) of the participating project countries. Trained young cancer survivors, their families and friends are ambassadors and coaches in each participating country and contribute to developing and sustaining a network of youth cancer survivors.

During two workshops organised by the under the EU Cancer Mission, followed by the conference "Addressing the needs of young cancer survivors" on 7 February 2023, it was indicated among others, that access to quality information for patients and caregivers is important in combatting cancer. Therefore, it is essential to maintain and further strengthen the EU Network of Youth Cancer Survivors and to try to make quality information in a user-friendly way available. This information should also be easily accessible online via different search engines. In addition, a communication campaign with dedicated events should also take place in different participating Member States and associated countries to increase and promote EU-CAYAS-NET.

This action supports the implementation of the Europe's Beating Cancer Plan to support childhood cancer and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The overall aim of maintaining the networks is to continue the collaboration between different existing stakeholder organisations and, through this network to further support social networking and further develop user friendly electronic tools to easily access the information and improve the links amongst individuals, patients, children, adolescents and young adults (CAYA) cancer survivors, carers, researchers, and social and health professionals active in cancer prevention and care across the Union and countries associated to the EU4Health Programme. In addition, a healthy lifestyle promoting network could also be integrated in mobile application and website. In addition, the network will consider relapse / metastatic cancer. The network should support and provide all the necessary information related to metastatic cancer.

The network will foster social networking, peer-support, coaching, knowledge-exchange, and aims at improving:

- a) the quality of life of survivors (including mental health, education and career support, follow-up care and transition);
- b) the care for adolescents and young adults (AYA) with cancer (including metastatic cancer);
- c) Equality, Diversity and Inclusion (EDI) along the whole treatment and survivorship trajectory;
- d) promote healthy lifestyles through interaction and exchange with peers, with people with a similar disease history, with friends as well as with healthcare organisations.

EXPECTED RESULTS AND IMPACT

The action will:

- a) improve the communication between children, adolescent, and young adult cancer survivors, formal and informal carers, and civil society;
- b) strengthen the knowledge on how to make a difference in the lives of young people with cancer and survivors;
- c) increase the knowledge and support for patients with relapse and metastatic cancer;
- d) allow survivors to learn how to become an advocate to bring key messages and knowledge on cancer survivorship to civil society.

The action contributes to Europe's Beating Cancer Plan flagship initiative on paediatric cancer, which specifically mentions the EU Network of Youth Cancer Survivors as being directly linked with the activities of the "Childhood cancers and cancers in adolescents and young adults: cure more and cure better" initiative. This initiative, supported under the Horizon Europe Cancer Mission, will directly benefit from the deliverables of this action.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|------------------------------------|-----------------------------|-------------------|
| Call for proposals – CR-g-24-45 | Q3/2024 | EUR 5 000 000 |

| Procedure type | Implemented by | Type of applicants targeted |
|---|-----------------------|---|
| Open calls for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations, associations, foundations, NGOs and similar entities |

CR-g-24-99 Call for proposals on Personalised Cancer Medicine

POLICY CONTEXT

Personalised Cancer Medicine ('PCM')¹⁰⁴ through particular methods and patient management, has the potential to improve healthcare by establishing technological advancements and implement the scientific understanding of disease processes within the cancer clinical pathway. However, PCM depends on the information management capabilities of the healthcare practitioners and other stakeholders working within health systems.

Future healthcare methods that make use of genetic/genomic testing and molecularly targeted medicines will contribute to preventing and better comprehending the disease processes. For instance, a thorough understanding of the metastatic process could point to novel therapeutic directions since metastasis are still the main cause of cancer-related mortality.

Electronic clinical decision support technology can be used to efficiently solve significant difficulties in patient management, ensuring the appropriate clinical use of genomic test data and molecularly targeted treatments.

This is accomplished by creating personalised preventative and treatment plans for individuals or groups, ensuring that patients receive the precise therapies that are most effective for them and that financial resources will not be put in ineffective procedures.

PCM can potentially improve cancer diagnosis and treatment outcome, as well as provide a better quality of life for patients and survivors, which is one of the main goals of the Europe's Beating Cancer Plan).

This action will support the Europe's Beating Cancer Plan objective to ensure high standards in 'Cancer diagnostic and treatment for all' and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the action is to complement the implementation of the 'Joint Action on Personalized Cancer Medicine' led by the Member States, thus helping to reduce the burden of cancer both at a personal and societal level, namely by supporting the Europe's Beating Cancer Plan and policy initiatives on personalised medicine. It may also support other Union initiatives that aim at improving public health, such as the '1+ Million Genomes' Initiative¹⁰⁵ and the Initiative to Understand Cancer (UNCAN.eu)¹⁰⁶ in so far as it shares the objectives of promoting personalised treatments and support ground-breaking research needed to advance the understanding of cancer mechanisms in order to improve the cancer care pathway.

This action should cover the ambition of the sixth flagship of the Europe's Beating Cancer Plan, the 'Cancer diagnostic and treatment for all' initiative. It will build on the results of the EU4Health Programme funded projects, such as the Personalised Cancer Medicine for all EU citizens ('PCM4EU')¹⁰⁷, the EU Cancer and Public Health Genomics platform project ('CAN.HEAL')¹⁰⁸, as well as the project for improved diagnostics and survival for all children with Acute Myeloid and the Leukaemia treated within the NOPHO-DB- SHIP consortium; a

¹⁰⁴ Council conclusions on personalised medicine for patients. ([2015/C 421/03](#))

¹⁰⁵ [European '1+ Million Genomes' Initiative](#).

¹⁰⁶ UNderstand CANcer ([uncan.eu](#)).

¹⁰⁷ Personalised Cancer Medicine for all EU Citizens ([PCM4EU](#)).

¹⁰⁸ [Can.Heal | Building the EU genomics platform \(canheal.eu\)](#).

cross-European collaboration ('CHIP-AML22').¹⁰⁹ The action will also make use of the guidelines, protocols and best practices, developed under other European Commission funded initiatives and projects such as the 1+ Million Genomes Initiative, a European-wide foundation to accelerate Data-driven Cancer Research (EOSC4Cancer)¹¹⁰, and Partnership on Transforming Health and Care Systems (THCS)¹¹¹ as well as Innovative Health Initiative (IHI)¹¹² funded projects could also be considered.

Activities will contribute to the Joint Action on Personalized Cancer Medicine', and include:

- a) the implementation of targeted projects involving civil society organisations and industry complementing the Member States' efforts in the design, planning and implementation of best practices (e.g., on metastatic cancer);
- b) the production of public health guidelines concerning personalised cancer medicine, genomic testing/screening and metastatic cancer management;
- c) patients and caregivers consultations, and other actions that can benefit citizens directly;
- d) preparation and roll out of innovative practices;
- e) support capacity building 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 benefit cancer patients accessing personalised cancer medicine services, which is expected to reduce the burden of cancer 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 (e.g., personalised cancer medicine, genomic testing/screening and metastatic cancer management) guidelines and, support for the preparation and roll out of new policy approaches; participation in the pilot testing of innovative practices; development of capacity building actions such as training and twinning, health communication or health literacy.

The actions that will complement the Joint Action on Personalized Cancer Medicine are expected to bring short-term improvements in implementing personalised cancer medicine and sharing best practice among Member States and countries associated to the EU4Health Programme. In the mid- to long- term, this is expected to improve innovation and patient management in the cancer pathway, including metastatic cancer, by improving knowledge and skills in implementing personalised medicine in oncology.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---------------------------------|-----------------------------|-------------------|
| Call for proposals – CR-g-24-99 | Q4/2024 | EUR 3 000 000 |

¹⁰⁹ [Childhood International Protocol – Acute Myeloid Leukaemia 2022](#)

¹¹⁰ European-wide foundation to accelerate data-drive cancer research ([eosc4cancer](#))

¹¹¹ [THCS at a glance \(thcspartnership.eu\)](#).

¹¹² [Innovative Health Initiative | IHI Innovative Health Initiative \(europa.eu\)](#).

| Procedure type | Implemented by | Type of applicants targeted |
|---|-----------------------|---|
| Open calls for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, public authorities, expert networks, civil society organisations, associations, foundations, NGOs and similar entities |

CR-g-24-96 Call for proposals to support the establishment of new networks of expertise on cancer and cancer conditions

POLICY CONTEXT

One of the flagship initiatives of Europe's Beating Cancer Plan is the establishment by 2025 of an EU Network of Comprehensive Cancer Centres, linking recognised Comprehensive Cancer Centres¹¹³, and cancer care networks in every Member State, to facilitate the uptake of quality-assured screening, diagnosis and treatment, innovative approaches including training, research, and clinical trials across the Union. The Cancer Plan aims to ensure that 90% of eligible patients have access to such centres by 2030. In addition, it aims at establishing new networks of expertise focusing on specific, challenging cancer conditions, which will benefit from cross-border cooperation and European expertise and will also link with the EU Network of Comprehensive Cancer Centres.

Under the EU4Health 2021 work programme¹¹⁴ a preparatory Joint Action ('JANE') has been launched to develop the concepts for new cancer networks of expertise¹¹⁵. This call for proposals aims to support the extension of the expert networks from Joint Action JANE under the EU4Health work programme 2023, and in particular to involve civil society, patient and health professional organisations in this work, which will be an important contributing factor in setting up these networks.

This action will support the Europe's Beating Cancer Plan objective to establish by 2025 an EU Network of Comprehensive Cancer Infrastructures and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

Activities will complement the joint action on new networks of expertise to be launched under the EU4Health work programme 2023 (CR-g-23-40.1-2), and include:

- a) implementing targeted projects involving patient organisations, civil societies, non-government organisations complementing the Member States' efforts in the design, planning and implementation of the networks;
- b) the establishment of best practices, the production of public health, treatment guidelines, or other actions that can benefit patients;
- c) the preparation and roll out of innovative practices (pilot tests), and support actions such as training and twinning, health communication or health literacy.

Support activities could include:

- a) practical support (to help patients better understand the impact of cancer and treatment; managing the side effects of cancer and cancer treatment);
- b) emotional support (regular consultations in support groups and workshops, aimed at supporting and helping patients to manage the difficult psychological and emotional impact of cancer);

¹¹³ European Guide on Quality Improvement in Comprehensive Cancer Control - page 96 ([CanCon_Guide.pdf \(ecpc.org\)](#)).

¹¹⁴ [EU4Health 2021 WP](#).

¹¹⁵ Joint Action on Networks of Expertise on Cancer ([JANE](#)).

- c) education and information (practical information on diet in cancer, oncology workshops for healthcare professionals and support personnel, tailored to specific types of cancer and their symptoms).

These resources will help guiding patients through their cancer journey by shedding light on some of the unknowns that come with a cancer diagnosis. The resources will also include a range of exercise classes and groups to suit individual needs (physical activities can help to reduce symptoms of anxiety, fatigue, improving patient mood and physical functioning); organising of survivorship groups for families and patients for education of special techniques and acquiring skills for dealing with stress and anxiety with cancer; mindfulness resources and programmes to help patients and their families to improve and maintain their wellbeing; manage the emotional challenges that a cancer diagnosis and treatment can present that can be an important part of the patient cancer journey.

EXPECTED RESULTS AND IMPACT

The expected result is to enable stakeholders to contribute to the delivery of the joint action on new networks of expertise launched under the EU4Health work programme 2023. This will include of establishing within the networks of expertise supporting actions for patients, families, caregivers and other participants in the fight against cancer. This action will help Member States to improve cooperation among their cancer services and with health professionals and patient advocates (by for instance addressing skill gaps and better equipping the health workforce in cancer care); and to improve and deepen the cooperation with the non-governmental sector.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|---|
| Call for proposals– CR-g-24-96 | Q2/2024 | EUR 1 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open calls for proposals (action grants) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations, foundations, NGOs and similar entities |

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE

4.1 IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND STRATEGY

HS-g-24-54 Direct grants to Member States' authorities: Pricing and Reimbursement Authorities – to step up national work and collaboration in the group of National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers ('NCAPR')

POLICY CONTEXT

The affordability of medicines poses a growing challenge for the majority of Member States as high-priced medicines put the financial sustainability of health systems at risk. This in turn reduces the possibilities for patients to have access to the medicines they need.

Decisions on pricing and reimbursement of medicines are a national responsibility. The Pharmaceutical Strategy for Europe announced actions to develop cooperation in a group of competent authorities, based on mutual learning and best practice exchange on pricing, payment, and procurement policies, to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers ('NCAPR') from an ad-hoc forum to a continuous voluntary cooperation. The NCAPR developed a shared plan of action aimed at tackling common challenges pertaining to pricing, payment, and procurement policies. Since the endorsement of this work plan, the group remained committed to executing on their objectives through three primary work streams:

- a) efficiency and affordability for health systems' sustainability;
- b) transparency, costing and pricing principles;
- c) innovative ways for payment methods, procurement models, novel pricing, and financial protection.

As a result of the relaunch of the NCAPR, the readiness to collaborate at the Union level has been affirmed and strengthened, paving the way for a more structured form of cooperation to be implemented. Through this joint action, the Commission is committed to supporting information exchange among national authorities and supporting national capacities on pricing, reimbursement, and payment policies.

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 and has a Union added value.

This joint action will contribute to the policy priority to implement the Pharmaceutical Strategy for Europe as it concerns the support of Member States in national pricing and reimbursement policies. It implements the EU4Health Programme's general objective to improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this joint action is to develop technical tools and implement actions to support and step up the voluntary cooperation among pricing and reimbursement authorities and public

healthcare payers; and as a result, strengthen national capacities to address common challenges related to pricing, reimbursement, procurement, and payment of medicines.

The joint action will build on the established cooperation of the NCAPR members over the past years. The joint action will work under a strategic guide and report to the NCAPR Group. It will provide technical expertise, human resources and infrastructure to implement the NCAPR actions between Member States authorities.

The actions will among others focus on the following priority topical areas, including those identified by the NCAPR during the 22 June 2023 plenary:

- a) generating evidence and addressing uncertainty;
- b) enhancing cooperation and joining forces in negotiations;
- c) moving towards a demand/needs-driven system;
- d) ensuring budget sustainability through competition;
- e) adapting and preparing for a changing legal landscape;
- f) increasing collaboration across the different decision-makers active in the lifecycle of a medicine; and
- g) leveraging the potential of data sharing.

Specific activities could include:

- a) mapping of and guidance on existing pricing and reimbursement policies of interest (e.g., conditional reimbursement systems);
- b) defining minimum evidence requirements for pricing and reimbursement applications;
- c) developing educational material or strategies to improve communication to industry and the public (e.g., on evidence requirements, limits of willingness-to-pay, biosimilars);
- d) developing common templates (e.g., for negotiations);
- e) conducting pilots (e.g., to explore the use of joint negotiation);
- f) developing an approach to moving from a supply driven to a demand/needs driven system;
- g) developing tools to support pricing and reimbursement decisions (e.g., on pricing and reimbursement status, on criteria for willingness-to-pay);
- h) developing guidance on the use of real-world evidence for pricing and reimbursement decisions, taking into consideration existing initiatives such as the EHDS and DARWIN-EU;
- i) supporting further data collection on prices, such as through the EURIPID database (e.g., with indicators to measure access, through automatization using application programming interface ('API') or webservices, fact sheets and capacity-building);
- j) reinforcing existing or new cross-country collaborations.

EXPECTED RESULTS AND IMPACT

The expected result in the short term is to strengthen the NCAPR members' capacities and to provide them with an improved environment to develop and implement national policy actions.

Specific outputs will feed into the NCAPR work plan, and might take the form of:

- a) in-person events bringing together authorities and stakeholders, dedicated working groups and webinars;
- b) mapping exercises, analyses or studies;
- c) guidance documents, methodology papers, toolboxes, training courses, best practice workshop or educational materials;
- d) technical tools supporting data sharing via existing platforms.

In the longer term, Member States will be better equipped to make use of their national decision-making capacities towards the Pharmaceutical Strategy’s goal, to ultimately improve access to affordable medicines across the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants – HS-g-24-54 | Q1/2024 | EUR 2 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States’ authorities |

HS-g-24-104 Direct grants to Member States’ authorities: Effective use of regulatory flexibilities including the use of magistral preparations that might be used to mitigate certain shortages

POLICY CONTEXT

The Pharmaceutical Strategy for Europe and more recently the Commission communication “Addressing medicines shortages in the EU”¹¹⁶ highlighted that shortages of medicines have been a serious concern in the Union for several years and have increased during the COVID-19 pandemic and recent winters, where many Member States experienced critical shortages of certain products, endangering the health of patients. These critical shortages were the result of several factors including supply chain dependencies and changing infection patterns which strongly increased demand. This underlines the need for a continued effort – from the industry, as well as from the Member States and at the Union level to address the issue of critical shortages building on the initiatives that have already been taken in recent years and the recently proposed reform of the Union pharmaceutical legislation.

Regulatory flexibilities in the application of the Union’s legal framework for medicinal products can be an important tool to manage and mitigate shortages of critical medicines. They include measures to facilitate the upscaling of production or approval of alternative suppliers of raw materials or finished products; temporarily extending shelf-life; or measures to facilitate redistribution between Member States. Moreover, flexibilities in terms of language requirements and multi-country packs may allow the easier distribution and re-distribution of available stocks across Member States. Finally, magistral preparations might be used to mitigate certain shortages.

Over recent years, Union regulators have gained experience with those flexibilities, especially during the COVID-19 pandemic. This offers confidence that they can be used under certain conditions without compromising safety and quality standards.

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 and has a Union added value.

This joint action will contribute to the policy priority to implement the Pharmaceutical Strategy for Europe and the Commission communication “Addressing medicines shortages in the EU” as it concerns the support of Member States in mitigation of critical medicines in the EU. It implements the EU4Health Programme’s general objective to improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this joint action is to promote effective use of regulatory flexibilities, collect knowledge and regulatory experience, support better collaboration between members of the Union's regulatory network and best practice sharing and contribute to mitigating where necessary the shortages of critical medicines in the EU.

¹¹⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. [COM \(2023\)672 final](#).

EXPECTED RESULTS AND IMPACT

This joint action is expected to result in:

- a) the development of knowledge and regulatory experience on the effective use of the available regulatory flexibilities both at Union and at national level to address shortages of critical medicines while continuing to ensure quality as well as patient safety;
- b) the exchange of best practices between Member State authorities;
- c) the fostering of collaboration between Member State authorities;
- d) where necessary, the development of proposals for guidance for the implementation of regulatory flexibilities at national level in line with Union legislation.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|------------------------------------|
| Direct grants – HS-g-24-104 | Q3-Q4/2024 | EUR 2 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States (joint action) in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

4.2 IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES

HS-g-24-63 Direct grants to EU reference laboratories for the Union contribution to *in vitro* diagnostic medical devices

POLICY CONTEXT

EU reference laboratories ('EURLs') are a crucial new type of scientific bodies in the diagnostics sector put in place by 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.¹¹⁷ These laboratories carry out a number of tasks for high-risk diagnostics, including e.g., infection control tests for blood transfusions and SARS-CoV-2 tests. Part of the EURLs tasks is funded by fees from notified bodies and Member States, but a significant part may not be covered by fees. Funding for EURLs is especially crucial in the setting up phase to ensure a successful start and provide the necessary predictability for the laboratories to carry out their tasks, which are essential for the successful implementation of Regulation (EU) 2017/746 on in vitro diagnostic medical devices ('IVDR'). Article 100(6) of Regulation (EU) 2017/746 provides for a Union contribution for EU reference laboratories which is essential to enable these tasks to be fulfilled.

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 the established EU reference laboratories, which solely have the required competence and responsibility to implement the action. Funding for EURLs is especially crucial in the setting up phase to ensure a successful start and provide the necessary predictability for the laboratories to carry out their tasks, which are essential for the successful implementation of the IVDR.

It implements the EU4Health Programme's general objective of strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c), (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will support the functioning of the EU Reference Laboratory network that is formed in accordance with Article 100(5) of Regulation (EU) 2017/746 and its activities, in particular the application of coordinated methods, procedures and processes, developing, applying and maintaining a peer review system, organising regular quality assessment tests, etc.

The action will support the tasks of the EU reference laboratories that may not be covered by fees, such as scientific and technical assistance to the Commission, providing scientific advice on state of the art, contribution to the development of common specifications and international standards.

EXPECTED RESULTS AND IMPACT

This action will enable the EU reference laboratories to carry out the tasks provided by Regulation (EU) 2017/746. It will also contribute to the establishment of a uniform and robust regulatory environment for diagnostics in the Union. This action will contribute to a high level of safety and performance of high-risk in vitro diagnostic medical devices in the Union.

¹¹⁷ OJ L 117, 5.5.2017, p. 176.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|--------------------------------------|
| Direct grants – HS-g-24-63 | Q2-Q3/2024 | EUR 5 500 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to the EU reference laboratories in accordance with Article 195, paragraph 1, points (d) of Regulation (EU, Euratom) 2018/1046 | HaDEA | Designated EU reference laboratories |

5. DIGITAL (DI)

DI-g-24-75 Direct grants to Member States' authorities: Expansion of MyHealth@EU

POLICY CONTEXT

On 3 May 2022, the Commission presented a proposal for a Regulation on the European Health Data Space ('EHDS')¹¹⁸, one of the central building blocks of a strong European Health Union. The proposed regulation supports individuals to take control of their health data and aims at improving the use of health data for healthcare purposes (primary use of health data), and facilitating better research, innovation, policy making and official statistics (secondary use of health data). In the proposed EHDS Regulation, MyHealth@EU is the infrastructure for the exchange of electronic health data across borders.

The MyHealth@EU infrastructure has already been set up by the Commission and the Member States based on the current framework under 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.¹¹⁹ It is implemented by National Contact Points for eHealth ('NCPeH') in Member States. MyHealth@EU has enabled the cross-border exchange of patient summaries and ePrescriptions. Most of the Member States are already either running these basic services in routine operations or developing them. However, some patient summary and ePrescription services are still not operational and their development has not yet been launched in a few Member States. It is important to close these gaps, to ensure the availability of these basic services for patients and health professionals in all participating countries.

In addition to the patient summary and ePrescription services, MyHealth@EU will support the exchange of other priority data categories defined in the planned EHDS Regulation: laboratory results and reports, medical imaging studies and reports and discharge reports. These services are currently being deployed by some Member States. There is a need to support Member States to develop and deploy these new services after finalising the set-up of the basic services, i.e., sending and receiving patient summaries and ePrescriptions, and to support third countries in conducting preparatory activities.

This action will advance the rollout of MyHealth@EU based on the work already carried out under multiple projects in Member States funded by the Connecting Europe Facility ('CEF') Telecom programme and under the EU4Health work programmes 2021 to 2023, and it will ensure complementarity between them and non-duplication of efforts.

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.

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

OBJECTIVES, SCOPE AND ACTIVITIES

¹¹⁸ Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. [COM/2022/197 final](#).

¹¹⁹ [OJ L 88, 4.4.2011, p. 45](#).

The objective of this action is to support the expansion of MyHealth@EU, including preparatory work, to enable patients to access its MyHealth@EU services and to progress towards a wider range of MyHealth@EU services offered.

Based on the specific needs and the situation of each Member State, this action includes activities by EU Member States authorities' for:

- a) the setting up of the NCPeH for ensuring the exchange of the ePrescriptions and patient summaries in those countries where the NCPeHs have not been implemented;
- b) the roll-out of ePrescription and patient summary services in the countries that have not yet launched these services;
- c) developing and deploying new services (laboratory results and reports, medical imaging studies and reports, discharge reports) in those EU Member States that have already launched routine operations for the full set of basic services (exchange of patient summaries and ePrescriptions in both directions).

The activities in this action also include supporting authorities in third countries associated to the EU4Health programme in conducting preparatory activities (e.g., analysis, design, and development activities) for the MyHealth@EU services described above.

EXPECTED RESULTS AND IMPACT

This action will contribute to an increase of the number EU Member States and patients using MyHealth@EU, ensuring the availability of basic services in all Member States and enabling the enhancement and expansion of the services.

By further 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. It will contribute to reinforcing citizens' security and trust. The action will contribute to the implementation of the future EHDS.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|------------------------------------|
| Direct grants – DI-g-24-75 | Q3/2024 | EUR 7 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Member States' authorities |

DI-g-24-76 Call for proposals on advancing the adoption of artificial intelligence in health

POLICY CONTEXT

Recent advancements in AI combined with the abundance of electronic health data have the potential to revolutionise healthcare and deliver concrete benefits to patients. However, studies conducted by the Commission in 2021¹²⁰ have revealed a slow and limited uptake of AI systems in healthcare and identified AI specificities in healthcare.

The SANTE 2021 study¹²¹ identified several interrelated gaps that explain the slow uptake that can be grouped in three main areas from a regulatory and governance point of view:

- a) the absence of a harmonised regulatory framework that addresses specificities of AI systems in health;
- b) the lack of an appropriate enabling environment for the flourishing of AI;
- c) the lack of trust and transparency regarding the use of AI.

Co-legislators also recognise the challenges of AI in healthcare. The European Parliament identified and clarified clinical, social and ethical risks posed by AI in healthcare and proposed mitigation measures and policy options in its 2022 report.¹²²

Since 2021, the Commission has proposed three main horizontal legal frameworks applicable to AI in healthcare, namely the Proposal for a Regulation laying down harmonized rules in artificial intelligence and amending certain Union legislative Acts (AIA)¹²³, the Proposal for a Directive on liability for defective products ('PLD')¹²⁴, and the Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence ('AILD')¹²⁵. Additionally, the Commission has proposed a sector-specific legal framework through its Proposal for a Regulation on the European Health Data Space EHDS¹²⁶, which contains rules for organising health data for primary and secondary uses.

The aforementioned studies are a good basis for better understanding the ecosystem and some of the challenges concerning AI in the healthcare but are not enough to identify the challenges and accelerators related to the deployment of AI in clinical practice, taking into account the acceleration of AI since 2021. While the majority of Commission initiatives and proposals on AI have focussed on the trustworthy development of AI, there is a need to identify and assess the challenges and accelerators related to its deployment. Deployment in the context of the study should be defined as the effective incorporation of AI into healthcare with a particular focus on clinical practice.

¹²⁰ [Study on health data, digital health and artificial intelligence in healthcare.](#)

¹²¹ Study on eHealth Interoperability of Health Data and Artificial Intelligence for Health and Care in the EU. [Final Study Report.](#)

¹²² [Artificial intelligence in healthcare. Panel for the Future of Science and Technology.](#)

¹²³ Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules in artificial intelligence and amending certain Union legislative Acts. [COM\(2021\)206 final.](#)

¹²⁴ Proposal for a Directive of the European Parliament and of the Council on liability for defective products. [COM\(2022\)495 final.](#)

¹²⁵ Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive). [COM\(2022\)496 final.](#)

¹²⁶ Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. [COM\(2022\)197 final.](#)

For AI to be deployed in clinical settings and provide concrete benefits to individuals including patients, it has to create among others, trust and acceptability, and it has to provide an environment of transparency and show the added value in clinical environments.

Consequently, it is essential to explore and comprehend the ecosystem surrounding AI in clinical practice. In this regard, it is necessary to bring together developers of AI, managers of healthcare facilities, users of AI (e.g., healthcare professionals) and those subject to AI predictions (e.g., patients) to better understand this new ecosystem, identify bottlenecks and challenges, and show how to successfully accelerate AI deployment in clinical practice.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The overarching objective of this project is to accelerate the safe deployment of AI systems in particular in clinical settings. One project is expected to be funded under this call.

The activities for this action should include the following actions:

- a) the setting up and running of one or more communities of experts (e.g., healthcare professionals who have experience in using/implementing AI in clinical practice and hospital managers who have experience in implementing AI solutions in healthcare organisations) and relevant stakeholders (e.g., developers of AI or AI based products and services, and patients) for delving into the potentials and challenges concerning AI deployment in clinical practice. In this respect, this should provide proposals on how to ensure sustainability of this expert community beyond the end of the project;
- b) the analysis and identification of the factors that lead to the successful and less successful deployment of AI in healthcare as well as challenges and obstacles, in collaboration with the expert community or communities mentioned under point a) and taking into account existing studies and projects. Two particular areas of interest that should be included are AI in cancer and AI in remote areas and medical deserts;
- c) the preparation of good deployment practices for AI in healthcare, recommendations and guidelines tailored to the needs of the specific users/environments in healthcare to accelerate the safe and effective deployment of AI in clinical practice in collaboration with the expert community or communities mentioned under point a) and taking into account existing studies and projects. This could include, e.g., how to address the diverse performance of AI systems in diverse clinical environments beyond reasons attributed to training/validation data and how the system was technically developed; how to address issues related to AI interaction with clinical workflows; obstacles related to ethical issues of AI in healthcare, AI-physician collaboration and impact on the doctor-patient relationship, as well analysis of risk of bias and how to address it;
- d) the design, development, and execution of pilots to test and evaluate in diverse real-life environments the expert community(ies)'s developed good deployment practices, guidelines and recommendations. As part of the pilots, to analyse how clinical practice is changing with the incorporation of AI systems. Based on the findings from the pilot projects to update, if needed, the proposed good AI deployment practices and other recommendations and guidelines;
- e) the development of user friendly interactive digital tool(s) that allows for the collection and communication of AI solutions successfully deployed in different clinical settings. The tool(s) should provide information on how the AI solutions are deployed to identify appropriate and useful information that should be indicated within the digital tool(s) that

would be developed. The aim of such digital tool(s) is to engage relevant stakeholders and to support the formation of communities (e.g., develop contacts and, to enhance collaborations between the experts or healthcare professionals who are using AI tools in clinical practice or who are interested to the uptake of AI in their medical domain, to bring together healthcare centres using AI as well as those interested to deploy AI, to connect developers of AI with users of AI and enable patients to obtain valuable information on AI uses in clinical practice). These tools should be continuously fed with new updated information by the members of the community and other AI users. In this respect, the beneficiary should provide a proposal on how this system could be best updated and how to ensure sustainability of this system beyond the end of the project;

- f) the organisation of workshops and communication activities (e.g., knowledge translation and dissemination of evidence-based practice/outcomes) addressed to different stakeholders (e.g., AI developers and users, hospital managers, the general public, patients). As part of these activities, to identify successful examples of AI deployment in healthcare and to provide an overview of these concrete success stories/good practices. These successful examples of AI deployment in healthcare should be displayed or included in the interactive digital tool mentioned in point (e). above. The beneficiary shall also produce other material (e.g., briefs, online campaigns) to explain and promote the safe, successful and trustful use of artificial intelligence in health to the relevant stakeholders and public;
- g) the provision of a summary of lessons learned and recommendations for potential policy measures that would contribute to accelerating the safe and effective deployment of AI in clinical practice.

EXPECTED RESULTS AND IMPACT

The action is expected to:

- a) create communities of experts with knowledge and experience on AI deployment in clinical settings;
- b) identify challenges and accelerators of the safe and effective deployment of AI in clinical practice;
- c) develop good AI deployment practices (e.g., appropriate incorporation of AI in clinical practice, ethics, etc.), guidelines and recommendations to speed up the safe and effective deployment of AI in health;
- d) test and evaluate through pilot projects how good deployment practices, guidelines and recommendations benefit diverse environments and diverse populations (e.g., metropolitan and rural hospitals). As part of the pilots, to analyse how clinical practice is changing with the incorporation of AI systems;
- e) expand knowledge on AI uses in medicine and develop trust on AI by both healthcare professionals and public including patients;
- f) prepare healthcare systems for full-scale application of AI;
- g) educate relevant actors (e.g., healthcare professionals, hospital managers, AI developers, patients) on the best use and practices of AI deployment in healthcare;
- h) educate individuals including patients on AI uses for diagnosis, treatment and management of patients;

- i) provide a reference interactive digital tool to collect and communicate best AI deployment practices in healthcare and foster collaborations and communities; and
- j) inform policy makers on the best way to accelerate the safe and effective deployment of AI in clinical practice.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|---|------------------------------------|---|
| Call for proposals – DI-g-24-76 | Q1-Q2/2024 | EUR 4 500 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grant) | HaDEA | Academia and education establishments, research institutes, hospitals, expert networks including ERNs, civil society organisations: associations, foundations, NGOs and similar entities; enterprises (incl. social enterprises and not for profit) in the field of public health private entities (for profit/not for profit) public authorities (public health, etc.) |

6. OTHER ACTIVITIES (OA)

OA-g-24-78 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 Regulation (EU) 2021/522 during the rotating Presidency of the Council with two conferences to be organised in 2024 or early 2025.

The action implements the EU4Health Programme's overall objective to improve human health throughout the Union and to ensure a high level of protection of human health in all Union policies and activities (Article 3, points (a) to (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) to (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

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

The 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

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, paragraph 1, 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 | Indicative call publication | Indicative Budget |
|---|-----------------------------|---|
| Direct grants – OA-g-24-78 | 2024 | EUR 200 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Direct grant to Member States in accordance with Article 195, paragraph 1, point (c), of Regulation (EU, Euratom) 2018/1046 | HaDEA | Presidency of the Council of the European Union |

OA-g-24-79 Call for proposals: action grants to contribute to the organisation of conferences and events

BACKGROUND

The work programme will support the organisation of conferences and events during 2024 or 2025 which will meet the objectives of Regulation (EU) 2021/522.

There is a need to timely identify upcoming health challenges and involve all interested parties such as citizens, patients, practitioners, scientists, policy makers from local, regional, and Union level, in finding possible solutions and alternative ways to address such health challenges; to provide information to individuals for preventing and responding to diseases; to join efforts with the beneficiaries of the Union funds to inform and communicate about the actions implementing the EU4Health Programme and the results obtained.

One of the ways to achieve this is by reaching out to the public and all relevant stakeholders in high level science-policy-society events that provide the optimal forum to facilitate the exchange of ideas and the development of feasible solutions.

The action will support the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, points (a) to (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) to (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to support the organisation of not-for-profit, Union-wide high-level science-policy-society events that bring together all interested parties such as citizens, patients, practitioners, scientists, policy makers from local, regional, and Union level. The events will cover important health topics that are related to the Union's health priorities, and thereby contribute to the development and implementation of the European Health Union.

The Commission considers that proposals requesting a contribution of EUR 150 000 would allow this specific challenge to be addressed appropriately.

These conferences are an opportunity for discussion on how to work better together at Union level on one or more health-related topics and will involve Member States, third countries associated to the EU4Health Programme and relevant stakeholders to exchange information and good practices on relevant topics in the field of public health.

Grants may be awarded to support the organisation of conferences and events that correspond to the general or specific objectives and the priorities of the EU4Health Programme, and which have a Union-wide dimension.

EXPECTED RESULTS AND IMPACT

This action will involve public or private entities with expertise on organising events in public health domain topics.

Applicants must clearly describe the expected number and profile/function of target participants in the event, including their distribution by Member States or third countries associated to the EU4Health Programme, organisation and type of expertise.

The events should include high level speakers, and a representative number of participants from all relevant fields of the challenges to be discussed.

The action will support communication activities addressed to the general public and/or to specific groups of people or professionals, in order to promote the European Health Union and its different initiatives.

Conferences and/or events must have a Union-wide dimension. The events will not focus on a specific condition or disease however, they will focus on current cross-cutting Union policy issues.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Indicative call publication | Indicative Budget |
|--|------------------------------------|---|
| Call for proposals – OA-g-24-79 | Q2-Q3/ 2024 | EUR 450 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Open call for proposals (action grants) | HaDEA | Public or non-profit entities with expertise in organising events in the public health domain |

B. PROCUREMENT

The overall allocation reserved for procurement contracts and administrative arrangements in 2024 amounts to EUR 318 443 856.

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

In 2024, 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, COMM) or European bodies (e.g., European Environmental Agency) to support priorities in the thematic areas listed below. The type of agreement will be identified according to the characteristics of the service.

ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

1. CRISIS PREPAREDNESS (CP)

CP-p-24-14 Ever-warm facilities (EU FAB) for vaccines production – the Commission’s 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 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 continue to make available this network of ‘ever-warm’ production capacities for vaccine manufacturing in the EU/EEA, 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. This action will continue to support the large-scale production of vaccines in the EU/EEA, to maintain and quickly guarantee access to sufficient production capacity in cases of public health emergency. The facilities must 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 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 at Union level in case of a future public health emergency and 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.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and support innovation regarding such products to enhance preparedness for future health emergencies in synergy with Horizon Europe. It implements the EU4Health Programme’s general objective of improving the availability, accessibility, and affordability of crisis-relevant products with a focus on pathogens with pandemic potential (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: use of existing framework contracts for the reservation of capacities and a priority right for manufacturing of vaccines (EU FAB)

Indicative budget for this thematic area: EUR 160 000 000

Implementation by: HaDEA

CP-p-24-15 Support to speed up the development of access to and/or uptake of medical countermeasures including critical medicines-(HERA)

HERA will identify the most promising and innovative technologies for diagnostic, preventive and therapeutic purposes, whose development, access or uptake should be supported. Furthermore, in case of a future public health emergency, the Commission may be tasked with establishing a list of crisis-relevant medical countermeasures and raw materials in accordance with Article 7(1) of Council Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.¹²⁷

This action is intended to allow HERA to support the development, access and uptake of medical countermeasures, including medicinal products, medical devices, *in vitro* diagnostic devices, PPE and other health technologies, necessary to improve preparedness and response to serious cross-border health threats. This also includes supporting late-stage clinical trials, clinical investigations, performance evaluation or similar studies for medical countermeasures needed to respond to health emergencies and critical medicines in shortage. In particular, this action will allow the mobilisation of funds to speed up development, market authorisation and access to innovative and repurposed medical countermeasures considered as a priority. This action will support economic operators developing, manufacturing and/or putting on the market innovative and/or repurposed medical countermeasures or treating, preventing or diagnosing priority health threats. The relevant countermeasures will be selected on the basis of the prioritisation exercises carried out by HERA (i.e., on health threats, the list of critical medical countermeasures, key antibiotics to anticipate the risk of critical shortages).

This action will also support the access in the Union to the critical medicines in a situation of vulnerability, as a response to the actions set out in the Communication: Addressing medicine shortages in the EU, COM (2023) 672 final.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and critical medicines, to support innovation and access regarding such products and to ultimately enhance preparedness for future health emergencies in synergy with Horizon Europe. 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 (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call(s) for tender for either framework contracts and/or service contracts.

Indicative budget for this thematic area: EUR 40 000 000

Implementation by: HaDEA

¹²⁷ [OJ L 314, 6.12.2022, p. 64.](#)

CP-p-24-16 Support innovation, supply capacity and access to critical medicines and antimicrobials (HERA)

Antimicrobial resistance (AMR) is a major threat to health, which was associated with 5 million deaths globally in 2019 and against which efficient medical countermeasures, including antimicrobials, are lacking. HERA has thus included AMR in its preliminary list of priority threats and commissioned in 2022 a study on “bringing more AMR MCM on the market” as well as a study on “stockpiling antimicrobials and Active Pharmaceutical Ingredients”. These two studies will provide evidence, including a mapping and prioritisation of medical countermeasures required to tackle AMR existing and in development AMR medical countermeasures, and an assessment of various policy options, which will help identify the most relevant actions for the Commission to promote the development, availability, and access to AMR medical countermeasures.

This action also aims at addressing the challenges identified in the Commission Communication ‘Addressing medicine shortages in the EU’¹²⁸, especially to boost Europe’s capacity to produce and innovate in the manufacturing of critical medicines and ingredients. EU FAB 2.0 will focus on critical medicines beyond antimicrobials, especially those in situation of vulnerability.

The activities to be covered by this action aim to promote the development, availability, supply and access to preventive, diagnostic and therapeutic medical countermeasures for AMR and critical medicines, notably through pull incentives, including but not limited to reserving capacities for the production or access to targeted products with a Union-wide marketing authorisation but also on products under development.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and can support their innovation and thus improve preparedness for future health threats and emergencies. This action also aims to address critical medicines and critical shortages, therefore protecting the health of patients. It implements the EU4Health Programme’s general objective of improving the availability, accessibility, and affordability of crisis-relevant products, with a focus on AMR and critical medicines (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call(s) for tender for either framework contracts and/or service contracts.

Indicative budget for this thematic area: EUR 50 000 000

Implementation by: HaDEA

¹²⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. [COM \(2023\)672 final](#).

ACTIONS WITH A COST BELOW EUR 20 000 000

1. CRISIS PREPAREDNESS (CP)

CP-p-24-17 Support to the Commission on gathering intelligence on priority threats and medical countermeasures (HERA)

HERA has carried out a threat prioritisation exercise and presented in July 2022 the three priority threat categories identified: pathogens with pandemic potential, chemical, biological, radio nuclear threats to health (CBRN)-related threats, and AMR-related threats. This threat prioritisation exercise has been complemented by the development of lists of critical medical countermeasures relevant for crisis preparedness and response, and the assessment of potential gaps in terms of the availability and accessibility, including research and development needs.

This action aims at providing continuous support to HERA in the identification of threats and their analysis, in the mapping and assessment of the availability of and accessibility to medical countermeasures and related intelligence gathering activities. These will inform the preparedness and response to cross-border health threats in terms of medical countermeasures.

This action supports the policy priority to be better prepared to respond to cross-border health threats. It contributes to the achievement of 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) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: use of existing framework contract(s)

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

CP-p-24-18 Establishment of a global wastewater sentinel system (HERA)

The current European wastewater-based infrastructure is still under development, and it is therefore critical to continue the institutionalisation of an effective wastewater surveillance system, to ensure that relevant data are promptly provided to competent health authorities at European level. There is a need to accommodate an increased sampling of the current supersites and to be able to enlarge the number of supersites. This action aims to ensure continuation and expansion of ongoing activities to a global dimension. This action should cover testing of wastewater samples on the request of the Commission in strategic sites through e.g., PCR analysis of SARS-CoV-2, PCR analysis of influenza and other pathogens, Next Generation Sequencing, with the specification of the platform to be used and samples management (controlled deliveries from collection points to the analytical facilities).

This action will also contribute to:

- a) building on and cooperating with the joint action on wastewater surveillance;
- b) complementing the Union sentinel system;
- c) cooperating with international stakeholders in a global effort;

- d) coordination at global level to organise simultaneous testing under pre-defined conditions.

This action supports the policy priority to be better prepared to respond to cross-border health threats. It contributes to the achievement of 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), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522

Indicative type of contracts/supply: use of existing framework contract, use of the existing Administrative Arrangement with JRC

Indicative budget for this thematic area: EUR 8 000 000

Implementation by: HaDEA

CP-p-24-19 Purchase, innovation and deployment of medical countermeasures in emergency situations (HERA)

The action aims to procure and supply essential crisis-relevant products and critical medicines for which security of supply needs to be assured in the Union at all times complementing Member States' reservation and stockpiling actions, as well strategic stockpiles developed at Union level. In particular, it will reserve capacities for the production and/or purchase of medical countermeasures in case of emergence or development of a serious cross-border health threat or recognised public health emergency or any other crisis that can have an impact on health at Union level. This action should also allow the supporting of intelligence gathering, research and innovation in emergency situation through clinical trials linked to specific countermeasures needed to address the emergency or by performing specific tests including sequencing in samples to detect a given threat.

The action will support and complement Member States' preparedness and response capacities as well as capacities of selected international partners. The activities will primarily focus on products with a Union marketing authorisation or CE marked but could also include products under development or not yet authorised/certified/placed on the market in the Union. The action aims at directly purchasing medical countermeasures or reserve manufacturing capacity and assigning these capacities for orders placed by the Union's contracting authorities and/or the Commission and to supporting intelligence gathering during emergencies.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures, including critical medicines in shortage, support their innovation and thus improve preparedness for future health threats and emergencies. It implements the EU4Health Programme's general objective of improving the availability, accessibility, and affordability of crisis-relevant products (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open procedures for either framework contracts and/or service contracts for the purchase or reservation contracts for the production and supply of relevant medical countermeasures, including their deployment or intelligence gathering of medical countermeasures use of existing framework contracts.

Indicative budget for this thematic area: currently no budget allocated. Budget will be mobilised in case of emergency.

Implementation by: HaDEA

CP-p-24-90 HERA's training and exercise programme for management of medical countermeasures (HERA)

Strengthening knowledge and skills in preparedness and response related to medical countermeasures is essential to improve European preparedness and response capacity to cross-border health threats and is one of HERA's main tasks. In close cooperation with Member States, HERA will implement a targeted training and exercise programme that will ensure the necessary capacity building to prepare and respond to health threats and to ensure supply-chain security for medical countermeasures in the continent, contributing to European and global health security. This action will also contribute to the 'Pact for Skills' of the EU Skills Agenda to tackle the most pressing industry skills gaps with active involvement of industry and key actors in education and training¹²⁹.

HERA's training and exercise programme is comprehensive, covering all aspects linked with the development, production and distribution of medical countermeasures, supporting the development of preparedness, readiness and actual response capacities of Member States to respond to a cross border health crisis, regardless of its nature. The training and exercise programme will also support policy development by looking at best practices, knowledge sharing and support communities of practice on relevant policy topics. It is also essential to continually strengthen coordination at Union level, ensure clear and swift decision-making procedures, streamline communication processes and the sharing of information. The best way of enhancing coordination and capacity building of relevant actors involved at Union and Member State level in the management of medical countermeasures in times of crisis, is through exercises (simulations), aimed at testing and improving existing preparedness and response frameworks, to which significant resources will be allocated. This action will also contribute to the complementary skills partnership for the health industry to be developed by the Commission by the end of 2023 as referred in the Communication from the Commission addressing medicine shortages in the EU¹³⁰. Finally, fellowships, staff exchange and twinning between Member States' services will also be part of the training and exercise programme.

Training activities will essentially target public health authorities and other relevant services (e.g., civil protection or defence) of Member States and countries associated to the EU4Health programme, industry, as well as actions in support of capacity building in non-EU countries, as part of HERA's international cooperation strategy. All activities will be developed in complement and looking for synergies with existent training programmes at EU, Member States, and international level.

This action supports the policy priority to be better prepared to respond to cross-border health threats. It contributes to the achievement of 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), of Regulation (EU) 2021/522)

¹²⁹ European Commission [Pact for Skills](#).

¹³⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. [COM \(2023\)672 final](#).

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

Indicative type of contracts/supply: use of existing framework contracts

Indicative budget for this thematic area: EUR 3 417 000

Implementation by: HaDEA

CP-p-24-5 Study supporting the ECDC Evaluation

In accordance with Article 31 of Regulation (EU) 2022/2370 amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, the Commission shall submit a report to the European Parliament, the Council, and the Management Board on the Centre's activities by 2025.

This action is to finance the external study (in line with better regulation guidelines) assessing the functioning of ECDC and which shall accompany the report on the Centre's activities.

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

Indicative type of contracts/supply: service contract using existing framework contract

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA / DG SANTE

CP-p-24-7 Union preparedness: Organisation of Trainings in the field of preparedness and response to serious cross-border health threats

This action has the objective to implement trainings for healthcare staff and public health staff in the field of preparedness and response to serious cross-border health threats according to Article 11 of Regulation (EU) 2022/2371¹³¹ on serious cross-border threats to health.

The trainings should be organised in close cooperation with the relevant Union agencies and bodies and professional health organisations and patient organisations, for healthcare staff, social service staff and public health staff in the Member States, in particular interdisciplinary One Health training, including on preparedness capacities under the International Health Regulation (IHR).

Those activities shall be organised in cooperation with the Member States concerned, as well as with the ECDC, in particular the EU Health Task Force, and in coordination, where possible, with the WHO. The activities will be building on current work towards a Union preparedness training programme.

When organising those programmes:

¹³¹ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/ [EU, OJ L 314, 6.12.2022, p. 26](#).

- (a) in cross-border regions, joint cross-border training, sharing of best practices and familiarity with public health systems for healthcare staff and public health staff shall be promoted;
- (b) account shall be taken of the contribution made by professional health organisations in each of the Member States.

This action implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening health systems by improving their resilience and resource efficiency (Article 3, points (b) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (i), of Regulation (EU) 2021/522.

Indicative type of contract/supply: service contract under existing framework contract.

Indicative budget for this thematic area: EUR 2 500 000

Implementation by: HaDEA

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1 TOBACCO POLICY

DP-p-24-20 Directive 2014/40/EU - Characterising flavours: operation of technical group

The implementation of 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 products¹³² entails the operation of a technical group of sensory and chemical assessors ('the technical group') assisting the Independent Advisory Panel (IAP) in determining whether tobacco products impart a characterising flavour. In view of the substantial change of circumstances regarding heated tobacco products, Article 7(12) of Directive 2014/40/EU has been amended in order to extend the prohibition of the placing on the market of tobacco products with a characterising flavour that already exists for cigarettes and roll-your-own tobacco, to heated tobacco products.

The activity will cover the operation of the procedure for determination whether tobacco products impart a characterising flavour (IAP + the technical group), in particular:

- a) sensory analysis of products;
- b) chemical analysis of products;
- c) supporting technical services on request the panel.

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

Indicative type of contracts/supply: service contract using an existing framework contract.

Indicative budget for this thematic area: EUR 600 000

Implementation by: HaDEA

DP-p-24-21 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 Union's 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 legislative framework for tobacco control is currently under evaluation (including the Tobacco Products Directive 2014/40/EU, Tobacco Advertising Directive 2003/33/EC and other related tobacco control policies across the Union) aimed at protecting public health and young people from tobacco related harm.

Over the last years, there has been a challenging and considerable change in the landscape of the tobacco and related products sector. A big variety of emerging products (e.g., heated tobacco products, nicotine-free e-cigarettes, and nicotine pouches) has entered the Union market, new virtual environments (including web shops and information society services such as social

¹³² [OJ L 127, 29.4.2014, p. 1.](#)

media) have surfaced and new public health interference strategies of tobacco and related industries have emerged.

The activities will cover the preparation of technical aspects addressing shortcomings of Directive 2014/40/EU (the Tobacco Products Directive) identified in the evaluation, including:

- a) data collection and analysis;
- b) development of health warnings for various product categories;
- c) development and validation of regulatory relevant product characteristics and their objective determination;
- d) better understanding of the social impact of tobacco and related products, in particular of emerging nicotine products.

The expected results are studies and reports providing specific technical input for ways of addressing problems identified in the evaluation of Directive 2014/40/EU and related legislation.

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

Indicative type of contracts/supply: use of existing framework contracts.

Indicative budget for this thematic area: EUR 900 000

Implementation by: HaDEA

DP-p-24-22 Tobacco Products Directive: operation of IT databases

The Tobacco Products Database provided the legal basis for the operation of two comprehensive reporting and monitoring systems for tobacco and related products and their tracing. In this respect, the Commission has been given specific tasks in running and/or monitoring of these systems.

The activities will cover the operation, maintenance and accompanying IT services for:

- a) operation and development the EUCEG product database;
- b) monitoring and oversight of the tobacco tracking and tracing system.

The Commission will continue to provide and develop the EU Common Entry Gate for the product reporting (including the helpdesk services) and the data storage facility for the Member States on the basis of the Service Level Agreement.

The Commission will also oversee and monitor the system for tracking and tracing of tobacco products and audits providers of primary and secondary repositories.

The result of this action is a smooth operation of the EUCEG product database and monitoring/oversight of the tobacco tracking and tracing system.

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

Indicative type of contracts/supply: existing framework contract.

Indicative budget for this thematic area: EUR 900 000

Implementation by: HaDEA / DG SANTE

3. CANCER (CR)

CR-p-24-38 Development of European guidelines and quality assurance scheme for gastric cancer prevention and care and preparing the third report on the status of implementation of the Council Recommendations on cancer screening

On 9 December 2022, the Council Recommendation (2022/C 473/01)¹³³ on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC was adopted. The new Council Recommendation is part of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan.

On gastric cancer prevention and care

In addition to the cancer screening programmes for breast, colorectal and cervical as recommended under the 2003 Council Recommendation, the new Recommendation suggests screening for lung, prostate, and under certain conditions, gastric cancer, specifically in those countries with the highest gastric cancer incidence and death rates. Through the Commission Initiatives on Breast and Colorectal Cancer, a system and streamlined methodology for the development of the European guidelines for cancer prevention, screening, and diagnosis and for the European quality assurance scheme covering the entire care pathway has been developed. Based on this existing methodology, guidelines for the screening of lung, prostate and gastric cancers will be developed as indicated in the Recommendation. While lung and prostate cancer, as well as certain elements covering gastric cancer are being covered through activities funded under the EU4Health work programme 2023, gastric cancer requires further investment, as the existing evidence and methodology has to be developed further and adapted to cover both primary and secondary prevention strategies.

The guidelines will be complemented by quality assurance manuals and tools to help the implementation and monitoring of their use in the Member States to support the further design, planning, and implementation of population-based and targeted cancer screenings, diagnosis, and treatment.

On the cancer screening report:

The first and second reports on the status of implementation of the 2003 European Council recommendations on cancer screening were published in 2008 and 2017 respectively. The reports highlighted the progress made in the Member States in rolling out of breast, cervical and colorectal cancer screening programmes. Through the second report, a set of common performance indicators at Union level were developed for the first time, and data was collected from different Member States to report coverage and quality of cancer screening programmes. The Cancer Plan stipulated that to guide further Union action on cancer screening with the most recent evidence, the Commission would launch work to prepare a third report on the implementation of the Council Recommendation on cancer screening. Alongside this, in the medium term, the upgraded European Cancer Information System (ECIS) would start to routinely collect indicators to monitor and assess cancer screening programmes.

In September 2022, the CanScreen-ECIS project was launched. The project coordinated by IARC will define indicators for breast, cervical, colorectal and lung cancer screening, design qualitative and quantitative data collection tools to report status and performance of cancer

¹³³ Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC ([OJ C 473, 13.12.2022, p. 1](#)).

screening and develop a data warehouse for data submission and data analysis. The project will implement a pilot to test functionalities of the new data warehouse and data analytics, at successful completion of which the warehouse and the analytics will be migrated to the ECIS by 2024. By providing the tools and the systems to collect and submit cancer screening data to the Member States the CanScreen-ECIS project will prepare the ground for the third report on status of implementation of the new Council Recommendation on cancer screening. The new report needs to take into consideration all the ongoing Commission Initiatives to improve cancer screening (e.g., the quality assurance schemes, risk-based cancer screening, piloting of prostate and gastric cancer screening).

The new Council Recommendation welcomes the Commission's intention to report on the implementation of cancer screening programmes, on the basis of the information provided by Member States, not later than the end of the fourth year after the date of adoption of the Recommendation.

This action can best be carried out by IARC, under the auspices and with guidance and collaboration of JRC, as it has the required expertise in relation to screening programmes and, in particular to work on guidelines on specific cancer sites where epidemiological considerations is a key factor for future implementation. The activities will be carried in collaboration with the JRC which oversees the further development of the underpinning methodology and, among others, shall guarantee the alignments between all upcoming initiatives on cancer for organised population-based screening programmes.

The objectives and activities will cover:

On gastric cancer prevention and care:

The overall aim is the development of evidence-based European guidelines, and a quality assurance schemes for particular consideration by those Member States with highest gastric cancer incidence and death rates allowing for a step-wise and gradual roll-out. The methodology developed in previous initiatives such as the Commission Initiative on Breast Cancer and on Colorectal Cancer should be applied. Preliminary analysis should be conducted on the epidemiological situation in Member States (and potentially also associated countries) to pursue a risk-based screening approach across the Union for the definition of the overall scope (e.g., indications of pathologies and targeted population) for the Commission Initiative on Gastric cancer.

On the cancer screening report:

The overall aim is the preparation of the 3rd Report on the Implementation of the Council Recommendation on cancer screening including to educate and guide the cancer screening programme managers to collect and submit cancer screening performance data using the new data collection tools to be able to estimate the new set of performance indicators. The project will target EU/EEA countries and associated countries to support collection of high-quality data across the cancer screening continuum for ongoing programme monitoring and quality improvement.

The expected results are the following:

On gastric cancer prevention and care:

- a) an established Working Group (expert panel) and conflict of interest assessments;
- b) final results of the epidemiological analysis;
- c) scoping of the development of the Commission's initiative on gastric cancer;
- d) development of risk assessment-model for gastric cancer guidelines;

- e) mapping of healthcare questions, available requirements and indicators on gastric cancer care;
- f) systematic reviews and evidence to decision frameworks;
- g) risk-based gastric cancer guidelines for primary prevention, screening and diagnosis;
- h) requirements and indicators covering the entire care pathway;
- i) quality assurance scheme manual that defines the accredited certification process in line with EC Regulation 765/2008 and the service requirements and indicators.

All outcomes will be published on the Commission's web hub hosted at the JRC for European guidelines and European quality assurance schemes within the context of organised and population-based screening programmes. This action will result in 'European guidelines for gastric cancer prevention, screening and diagnosis' and a 'European quality assurance scheme for gastric cancer prevention, screening and care' to support Member States to further design, plan, and implement population-based and targeted gastric cancer screenings and diagnosis where applicable.

As regards the cancer screening report:

- a) an established Working Group (panel of experts from different countries having access to cancer screening data) and conflict of interest assessments;
- b) Working Group members trained to be able to apply the data tools available through ECIS platform for data collection and submission;
- c) the collection and validation of information and data from different Member States and associated countries to report status, organisation and performance of screening programmes for breast, cervical, colorectal and lung cancer screening;
- d) collaboration with ongoing projects of the Commission established to collect information and data from the pilot prostate and gastric cancer screening programmes;
- e) collaboration with ongoing projects of the Commission established to develop indicators and data collection tools for risk-based approach to cancer screening and data collected from any such pilots;
- f) the 3rd report on the implementation of Council recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC prepared to include status, organisation and performance of breast, cervical, colorectal, lung, prostate and gastric cancer screening in the EU/EEA and associated countries;
- g) status of utilization of quality assurance scheme and the certification process is included in the report.

All outcomes will be published on the ECIS hosted at the JRC to disseminate the status, organisation, and performance of cancer screening programmes. Routine collection of cancer screening indicators through ECIS will support Member States to implement quality assured cancer screening to ensure that 90% of the eligible population have access to evidence-based cancer screening.

This action supports the new EU approach on cancer screening as part of the new EU Cancer Screening Scheme, one of the flagship initiatives of 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), of Regulation (EU) 2021/522) through the specific objectives in Article 4, points (a), (f) and (g), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: Negotiated procedure with IARC, under the auspices and with guidance and collaboration of JRC.

Indicative budget for this thematic area: EUR 6 500 000

Implementation by: DG SANTE/ HaDEA

CR-p-24-35 Exploratory study on the provision of care for Adolescent and Young Adult (AYA) cancer patients in the Union

Each year, more than 150 000 people in Europe in the AYA age range of 15–39 years, and over 1.2 million worldwide, are diagnosed with cancer. While cancer in adolescent and young adult (AYA) is relatively rare, it represents a substantial cause of death in this population group. Outcomes are often poorer than in younger (or older) patients with the same type of cancers, due to the different biological features of their tumours, which limit specificity and sensitivity to available therapies.

Because of their particular age group, being neither children nor adults, care provided in healthcare systems is often suboptimal, not targeted to their specific needs and challenges, such as age-specific supportive care, fertility counselling, appropriate psychological support, education and career development, body image, sexuality and relationships, alcohol/substance abuse etc. In addition, AYAs do not have the same health seeking behaviour as adults, making provision of prevention and care services even more complex. Both the clinical and psychological needs of AYA would require specialised centres or service networks, offering a multidisciplinary approach to diagnosis and care. The involvement of dedicated professionals such as mental health specialists, specialised nurses, supportive/palliative care specialists, social workers, physiotherapists, occupational therapists, experts in nutrition, fertility and sexuality with age-specific skills and experience is essential to correctly address AYA patients and survivors needs and provide optimal care, improving quality of life. While information on the availability of dedicated AYA services in Member States is rather scarce, available data seem to point to huge discrepancies within and across countries, contributing to exacerbating inequalities in the provision of cancer care. Inequality in the provision of *ad hoc* care to AYA patients and survivors in the Union as well as the related limited understanding and suboptimal management of acute and late effects of treatments were among the issues reported at the recent conference “Addressing the needs of young cancer survivors”, which the Mission on Cancer organised on 7 February 2023. It brought together young cancer patients and survivors, caregivers, policy makers and researchers to discuss challenges faced by young cancer patients and showcase successful initiatives.

Centralisation of care into dedicated specialist AYA services and networks (including day care services and outpatient clinics) has been suggested as the best way forward to effectively improve provision of care to AYA cancer patients and survivors. Yet, data available to allow an in-depth analysis to support the development of policy recommendations is limited.

With the proposed study, the Commission aims to better map the situation in Member States, with regard to the provision of healthcare to AYA cancer patients and survivors. The analysis should produce a clear picture of approaches available at national (or regional/local) level, including identification of hurdles for the integration of dedicated AYA services in healthcare systems. The study should also enable the identification of best practices and innovations into provision of care for AYA patients and survivors. For that, the study should draw from the involvement of all key stakeholders, including AYA patients and survivors, health professionals, public authorities and policy makers in order to identify barriers and enabling factors for the design and provision of quality care before, during and after treatment. The study should also look into synergies with EU-funded projects and initiatives in research and health

policy (for example, EU Network of Young Survivors, European Cancer Patient Digital Centre, PANCARE-FollowUp, Strong AYA etc.). Ultimately the study will support the development of policy recommendations to Member States.

The study will be essential to inform future policy actions.

The study should deliver a report, mapping the current situation at national and, where relevant, regional or local level with regard to measures in place for the provision of ad hoc support and care to AYA cancer patients and survivors. It should include several case studies, enabling peer-learning, and define best models for the provision of quality AYA care, including through the identification of best practice/success stories. The report should also include recommendation for future actions.

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

Indicative type of contracts/supply: open call(s) for tender for a service contract.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

CR-p-24-98 Boosting cancer prevention through continued maintenance of the EU cancer prevention app

One of the policy objectives of Europe's Beating Cancer Plan is to improve health literacy on cancer risks and determinants.

The European Code against Cancer¹³⁴, which was first published in 1987, has a long-standing tradition as a preventive tool aimed at reducing the burden of cancer by informing people on how to avoid or reduce carcinogenic exposures, adopt behaviours to reduce their cancer risk, or to participate in organised intervention programmes. The European Code against Cancer is being updated to take into account the latest scientific developments and to include new evidence-based recommendations to improve health literacy and to guide national health policies in cancer prevention.

Evidence demonstrates that the recommendations of the European Code against Cancer are only partially reaching the general population. Therefore, there is a need to improve its impact across the Union. To achieve this, an 'EU Mobile App for Cancer Prevention' is being developed as part of the BUMPER¹³⁵ project and a tender to Design, develop and delivery of an 'EU Mobile App for Cancer Prevention¹³⁶', aiming to extend the coverage of the European Code against Cancer and to empower citizens to make informed decisions as regards their own health.

The main objective of this action is to provide maintenance and further development of the 'EU Mobile App for Cancer Prevention' to include the 5th edition of the European Cancer Code against Cancer, and to continue extending the coverage of the European Code against Cancer in particular through communication on the app.

This action includes activities to:

¹³⁴ European Code Against Cancer - About the code (iarc.fr)

¹³⁵ EU4H-2021-PJ2 – Grant 101079924 – [BUMPER](#).

¹³⁶ [HADEA/2022/OP/0004](#).

- a) maintain the usability of the ‘EU Mobile App for Cancer Prevention’ by updating and further developing the content of the app, providing training, and ensuring promotion among the general population;
- b) integrate, among others, the recommendations of the 5th edition of the European Cancer Code against Cancer into the app;
- c) ensure the technical maintenance, and proper functioning and further technical development of the app;
- d) foster the usability of the app across the Union, and among the disadvantaged groups.

The expected results are to keep the content of the ‘EU Mobile App for Cancer Prevention’ up to date, in line with the latest recommendations of the European Code against Cancer, to ensure dissemination of the app across the EU, to provide and training as well as ensuring the technical functionality of the app. The action aims to reduce individual cancer risks across the Union through the application of the European Code against Cancer recommendations.

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

Indicative type of contracts/supply: Open call for tenders for a service contract.

Indicative budget for this thematic area: EUR 1 800 000

Implementation by: HaDEA

CR-p-24-97 Administrative, logistic and scientific support for the Sub-group on Cancer under the PHEG and for the EU-US Health Task Force (Cancer)

The Expert Group on Public Health advises the Commission on public health and health systems, in relation to non-communicable and communicable diseases. One of its sub-groups for examining specific questions, is the Sub-group on Cancer.

Europe’s Beating Cancer Plan (which was adopted in February 2021) presented ten flagship initiatives, and several other actions. It supports Member States’ work to prevent cancer and to ensure a high quality of life for cancer patients, survivors, their families, and carer’s and is structured around a number of key areas where the Union can add most value:

- a) prevention
- b) early detection
- c) diagnosis and treatment
- d) quality of life of cancer patients and survivors

The sub-group on cancer was set up to facilitate the governance of the implementation of the Europe’s Beating Cancer Plan and the Horizon Europe Cancer Mission and to ensure synergies between the two Commission initiatives. The purpose of this action is to provide support services to DG SANTE in its role as secretariat of the Sub-group on Cancer. The Secretariat has the responsibility to organise the meetings of the sub-group (online and in-person) as well as to provide administrative support to the sub-group.

In addition, the Commission has also set up a Stakeholder Contact Group as part of the governance structure of the Plan. This group has meetings several times a year to be updated

on the ongoing work and to be consulted on relevant topics as part of a wider stakeholder involvement.

There is increasing interest for the Europe's Beating Cancer Plan to enhance international cooperation on cancer with third countries. Policy dialogues with these stakeholders will help identify areas for future collaboration and serve as a platform for regular exchanges. Specifically in the cancer domain under the framework of the EU-US Health Task Force. In the initial phase this transatlantic cooperation will revolve around two technical working groups, one on paediatric cancer, and one on lung cancer.

In the context of all these groups and stakeholders, the activities requested are, for example, administrative coordination of the meetings (online and in-person ones), preparation of the relevant documents, welcome desk and registration, organisation of the catering, provision and operating of online meeting system.

Further to the meetings, there are several scientific background documents or studies that are required for the implementation of the Europe's Beating Cancer Plan, to help informed decision making according to the latest scientific advances. Expected results:

The results will provide the successful organisation of a number of meetings of the Sub-group on Cancer, the Stakeholder Contact Group, and with third countries' stakeholders including the appropriate follow-up, with a good satisfaction rate of participants. This will facilitate and synergise the implementation of the Europe's Beating Cancer Plan and the Horizon Europe Cancer Mission.

Other results would be a number of scientific background documents or studies carried out on time and in high quality in the required topics to provide evidence and support the implementation of Cancer Plan and Cancer Mission.

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

Indicative type of contracts/supply: specific service contract using an existing framework contract on meetings.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

4.1 IMPLEMENTATION OF REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

HS-p-24-47 Services for Administrative, Logistic and Communication support to the Secretariat of the Member State Coordination Group on Health Technology Assessment and HTA Stakeholder network

Regulation (EU) 2021/2282¹³⁷ on health technology assessment (HTA) was adopted on 15 December 2021 and entered into force on 11 January 2022. It will apply from 12 January 2025. Regulation focuses on clinical aspects of HTA and provides a permanent legal framework for the conduct at Union level of joint clinical assessments, joint scientific consultations, the identification of emerging health technologies and joint work on methodologies. It provides a complex governance system made of a Member State Coordination Group (HTACG) and four different subgroups covering the main activities above, as well as a consultative Stakeholder Network. The Commission is the Secretariat for this structure.

The purpose of this action is to provide support services to DG SANTE in its role as secretariat of the HTACG and support the joint work of the sub-groups including the remuneration of the authors/co-authors/ and assessors/ co-assessors for guidance documents and reports. The HTACG Secretariat has the responsibility to host the meetings of the HTACG and its subgroups at the Commission's premises, as well as to provide administrative support to the group and its subgroups. The HTACG has decided to establish subgroups for joint clinical assessments, joint scientific consultations, identification of emerging health technologies, development of methodological and procedural guidance. Additional subgroups or working groups may be established. A HTA IT platform users working group was also set up to ensure the involvement of users in the development of the HTA IT platform. The Commission has also set up a Stakeholder network to support the work of the HTACG and its subgroups upon request, which will meet at least once each year. In the context of all these groups, subgroups and networks, the activities to be carried out are, for example, administrative coordination of the meetings, preparation of the relevant documents, welcome desk and registration, organisation of the catering. For the meetings of the Stakeholder network the services will also include the identification of a suitable venue as well as the organisation and payment of travel and accommodation for participants.

The results will provide a successful organisation of a number of meetings of the HTACG, its subgroups and the Stakeholder network, as well as the IT platform users working group, including the appropriate follow-up, with a good satisfaction rate of participants.

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

Indicative type of contracts/supply: service contract using an existing framework contract.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

¹³⁷ 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 L 458, 22.12.2021, p. 1](#)).

HS-p-24-48 Conference –on the application of the Regulation (EU) 2021/2282 on Health Technology Assessment

Regulation (EU) 2021/2282 on Health Technology Assessment (HTA) was adopted on 15 December 2021 and entered into force on 11 January 2022. The HTA Regulation focuses on clinical aspects of HTA and provides a permanent legal framework for the conduct at Union level of joint clinical assessments, joint scientific consultations, the identification of emerging health technologies and joint work on methodologies. As such, it replaces the past system of voluntary network of national authorities, the “HTA Network, and the Union-funded project-based cooperation, the “Joint Actions EUnetHTA”. It provides for a complex governance system made of a Member State Coordination Group and four different subgroups covering the main activities, as well as a consultative Stakeholder Network. The Commission is the Secretariat for this governance structure, while working in parallel on the adoption of the implementing legislation, establishing a HTA Stakeholder Network and the set up and maintenance of an HTA IT platform. After three years of preparation, the HTA framework for joint HTA work will apply from 12 January 2025.

The objective of this action is the organisation of a conference to announce the application phase of HTA Regulation. This event should ideally take place between January and March 2025, with the primary objective of raising public awareness about the legal framework and taking stock of the work done during the preparatory phase. The conference should be organised in a hybrid format and take place outside the Commission premises in a suitable venue with multiple rooms to allow for breakout or parallel sessions. All Member States and stakeholders should be invited and involved in the development of the programme in different capacities. A strategy for live tweeting, Slido and general communication should be defined and implemented.

In the short term, the conference should provide a moment of reflection and an occasion for gathering stakeholders, national HTA agencies and authorities and EU institutions and agencies under one roof before the start of the joint work under HTA Regulation. The focus should be on explaining the functioning the Union’s new HTA Regulation. The event should also provide an important public moment where results achieved, and key challenges are discussed with a broader audience outside the usual HTA community.

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

Indicative type of contracts/supply: service contract using an existing framework contract.

Indicative budget for this thematic area: EUR 150 000

Implementation by: HaDEA

4.2 IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND PHARMACEUTICAL STRATEGY FOR EUROPE

HS-p-24-50 Implementation of pharmaceutical legislation and data-driven policy for medical products

Preparing the transition from the current pharmaceutical framework to the proposed measures under the pharmaceutical reform requires supportive actions and data. In particular, evidence-based and data-driven policy making is at the heart of the Commission's better regulation agenda, and the sector of medical products (pharmaceuticals and medical devices) is no exception to that. The sector plays a critical role in providing healthcare for Union citizens and is a major contributor to the Union's competitiveness. However, the data is scattered and complicated, the analysis requires specific expertise on the databases and on the functioning of the sector. Therefore, it is necessary that the Commission has access to sector specific data at EU, national, therapeutic area and product level too, together with the necessary capacities to analyse, present and visualise them.

The action aims to make the Commission the ultimate unbiased source of information on key metrics of the medical products sector in the Union, which is currently dominated by data and reports from stakeholders with vested interest.

This action can also cover testing or piloting innovative concepts proposed in the reform and other elements related to the implementation of pharmaceutical legislation.

The activities aim:

- a) to support the negotiations on the revision of the pharmaceutical legislation with facts and evidence – to counter the often-biased claims from stakeholders, notably from the industry;
- b) to publish unbiased analyses that serve as reference documents for the Union institutions, Member States and other stakeholders (similar to the OECD report 'Health at a Glance');
- c) to monitor progress on the political ambitions of the Commission;
- d) to create professional charts and other visuals that can support communication activities;
- e) to anticipate trends in the sector, and to use this foresight for policy actions;
- f) to be able to address quickly a crisis situation or an ad-hoc policy request;
- g) to improve the evidence base of policy-making;
- h) to maintain results available for future use;
- i) to establish a framework to address similar policy needs in the coming periods;
- j) to acquire knowledge required for the implementation of the pharmaceutical legislation;
- k) to implement the Pharmaceutical Strategy for Europe.

The results will be:

- a) fixed deliverables, for example annual reports or prompt replies to ad-hoc requests covering different aspects of the medical products (innovation, access, affordability, competitiveness);
- b) internal capacity building to enable in-house repetitive and simple data mining, answering questions immediately;
- c) outcomes from pilots testing specific concepts or similar supporting activities to inform the implementation of the pharmaceutical legislation.

The action would cover a broad scope of health interventions, with a primary focus being on medicinal products and medical technologies. Such combined approach would be an important step of overcoming the segmentation of silos and allow for a better insight into health innovations, many of which are now a combination therapy.

The impact will be better, more evidence-based policy making, and thus the Commission becoming the source of unbiased data and analytics of the sector with improved credibility.

This action implements the EU4Health Programme's general objective of improving availability, accessibility and affordability of medicinal products, medical devices, and crisis relevant products (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: DIGIT framework contract and/or open call framework contract and/or procurement of specific services (e.g., data acquisition / processing).

Indicative budget for this thematic area: EUR 1 128 000

Implementation by: DG SANTE and HaDEA

HS-p-24-52 IT support to the European Medicinal Products database ('EMP')

The purpose of European Medicinal Products database (EMP) is to support DG SANTE with the creation, maintenance, amendment, suspension, or withdrawal of medicinal products marketing authorization, on the basis of the scientific opinions received from the European Medicines Agency. To this purpose, the information system is constantly updated to maintain its efficiency and the quality of its output.

This action will provide a continuous IT support, maintenance, and update of the EMP.

The action supports the implementation of Union pharmaceutical legislation, and 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, (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service.

Indicative budget for this thematic area: EUR 450 000

Implementation by: DG SANTE

HS-p-24-53 Support the Pharmaceutical Inspection in Member States

The manufacture or import of medicinal products is subject to manufacturing or import authorisation. The authorisation holder must comply with the principles and guidelines of good manufacturing practice and use active substances (active pharmaceutical ingredients) which were manufactured in compliance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). A joint action on the quality has been launched in 2021 with the aim of:

- a) capacity strengthening of EU/EEA inspectors/auditors to ensure compliance with GMP and GDP in inspections and audits;
- b) improving compliance with the Union's pharmaceutical acquis and alignment with the pharma strategy;
- c) ensuring quality of the active pharmaceutical ingredients (API) imported from non-EU countries.

The aim of this action is to train GMP Inspectors/Regulators by Inspectors/Regulators and reach inspection excellence through harmonised training as well as to provide a platform for

discussion and sharing among Authorities and Regulators with a view to responding and identifying needs as well as contributing to global harmonisation and interpretation of GMP.

The following results are expected:

- a) training of inspectors;
- b) development and dissemination of training tools.

The above activities will contribute to the harmonisation of GMP and lead the Union development, implementation, and maintenance of harmonised GMP and GDP standards and quality systems of EU/EEA Inspectorates in the field of medicinal products. It will help addressing some of the very actual concerns such as encouraging global convergence in pharmaceutical and API manufacturing quality and inspection processes, addressing the challenges resulting from globalisation, in particular by the sharing and leveraging of resources, facilitating capacity-building, etc.

This action will contribute to the policy priority to implement the Pharmaceutical Strategy for Europe as it concerns the support Member States in training of the GMP and GDP inspectors. This action implements the EU4Health Programme's general objective to strengthen health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: specific contract under an existing framework contract or launch call for tenders.

Indicative budget for this thematic area: EUR 200 000

Implementation by: HaDEA

HS-p-24-55 Study on the implementation of Regulation (EU) 536/2014 on clinical trials on medicinal products for human use

Regulation (EU) 536/2014 (the 'Clinical Trials Regulation'¹³⁸) applies since January 2022 and replaces the Clinical Trials Directive 2001/20/EC. The new Clinical Trials Regulation reinforces the harmonisation of the clinical trial applications assessment, provides an IT portal as a one stop shop for clinical trials in the EU, guarantees the evaluation of these applications in fixed deadlines, and ensures a greater transparency for clinical trial data.

In accordance with Article 97 of the Clinical Trials Regulation, the Commission is to present a report to the European Parliament and to the Council on the application of the Regulation five years after the date of application of the Regulation (i.e., by 31 January 2027).

The report shall include an assessment of the impact that the Clinical Trials Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The Commission is to, if appropriate, present a legislative proposal based on that report in order to update the Clinical Trials Regulation provisions.

¹³⁸ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. ([OJ L 158, 27.5.2014, p. 1](#)).

The objective of this activity is to conduct a study that will prepare the report on the application of the Clinical Trials Regulation.

The contractor will gather data and feedback from all interested parties (sponsors, investigators, patient organisations, EMA, Member States competent authorities, ethics committees, etc.) in order to:

- a) analyse the different types of clinical trials authorised under the Clinical Trials Regulation;
- b) assess the impact of the Clinical Trials Regulation on scientific and technological progress;
- c) propose measures to improve and maintain the competitiveness of European clinical research.

Amongst other tasks, the contractor will analyse data gathered by EMA on the clinical trials applications in CTIS, the IT portal that streamline all applications for clinical trials in the EU, including the Key Performance Indicators selected for the monitoring of clinical trials and the survey reports generated on a yearly basis to collect feedback directly from commercial and non-commercial sponsors.

The contractor will organise and conduct bilateral interviews and workshops to collect the views from all stakeholders on the Clinical Trials Regulation, how it is implemented and what can be improved, including, as the case may be, proposals for measures required to maintain the competitiveness of European clinical research.

The action supports the implementation of Union pharmaceutical legislation, and 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, (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: request for service using the framework contract on Better Regulation.

Indicative budget for this thematic area: EUR 338 000

Implementation by: HaDEA

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

HS-p-24-57 Regulatory coherence on Substances of Human Origin based therapies

An increasing number of innovations in biotechnology contains and combines technologies that are regulated under different Union legal frameworks of Substances of Human Origin (SoHO) (blood, tissues and cells, organs), pharmaceuticals (including Advanced Therapy Medicinal Products) or medical devices. In addition, other union legal frameworks are increasingly playing a role to allow access to safe and effective new therapies, including food legislation, health technology assessments, clinical trials and cross-border healthcare. There is a need for effective interactions between the SoHO authorities and all the relevant authorities in these other legal frameworks, in order to ensure access to safe and effective innovative biotechnologies.

Through a set of workshops, this action will bring together SoHO authorities and relevant counterpart authorities, at national level as well as at union level (e.g., EMA and ECDC) to build a relationship, common understanding and mutual trust, focusing on how to best handle SoHO-based therapies. The workshops will be prepared through a set of online meetings with leading authorities in the different sectors. Common aims and activities can include:

- a) identifying key needs and topics that require mutual exchange, common understanding and alignment between SoHO authorities and the authorities set-up under each of the other relevant legal frameworks;
- b) development of common sets of guidance for alignment of technical requirements/standards on safety and quality to improve efficient interplay, avoiding gaps and overlaps, between SoHO and other relevant legal frameworks, where identified as useful;
- c) development of common sets of guidance for alignment of oversight tasks (vigilance, traceability, inspections, authorisations) to improve efficient interplay, avoiding gaps and overlaps, between SoHO and other relevant legal frameworks, where identified as useful;
- d) development of common protocols for the alignment of collection and exchange of data to improve common understanding across sector authorities, including for activity, vigilance, and outcome monitoring;
- e) development of an approach for future consultation and coordination between the SoHO authorities and each of the other sector authorities (triggers, procedures, timelines) – in line with the future SoHO Regulation;
- f) development of common training/education to strengthen a common cross-sector understanding on technical requirements and oversight (authorisation, inspection, vigilance).

This action supports the implementation of the future legislative framework for Substances of Human Origin and its coherence with other union legal frameworks. 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 the strengthening of health systems by improving their resilience and resource efficiency (Article 3, points (c) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (f), (g) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: use of an existing framework on meetings.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

HS-p-24-59 Organisational support to Member States to implement the new Regulation on Substances of Human Origin

The Commission's proposal for a new SoHO Regulation contains new requirements for Member States that they would need to comply with as of the application, proposed to be around 2026. These requirements would need to be complied with by the public blood and transplant services as well as by the national authorities in charge of oversight.

This action will help individual Member States with their preparation and provide guidance for implementing these organisational changes. This support can come in multiple forms including tailored assessments of the current situation, identification of gaps to bridge, change management strategies and action plans, twinning actions and trainings. Within one envelope, several country-specific workstreams will be organised in function of the (areas of) needs brought forward in each of the Member States. The parallel workstreams will benefit from coordinated management and opportunities for common work and expertise to the benefit of multiple countries with similar needs.

This action will prepare these public actors for implementing the proposed SoHO requirements, that entail in particular following new activities:

- a) registration of entities, authorisation of establishments and of importing entities;
- b) risk-based inspection schedule of establishments and possibly of entities;
- c) application and authorisation for new preparations, including the collection and assessment of clinical outcome data;
- d) provision and collection of activity data, monitoring of critical SoHO and alerts for disruptions;
- e) national and local emergency plans;
- f) protection measures for donors and for offspring;
- g) coordination between national SoHO authorities, with national authorities of other sectors and with the SoHO Coordination Board;
- h) joint inspections, joint assessments and Commission controls.

This action supports the implementation of the future legislative framework for Substances of Human Origin and 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, (Article 3, points (c) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (f), (g), (h) and (i) of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service under existing framework contract or using a framework contract with DG REFORM.

Indicative budget for this thematic area: EUR 5 400 000

Implementation by: DG SANTE/HaDEA

HS-p-24-60 Development of SoHO digital platform – SoHO-X

Chapter XI of the proposed SoHO Regulation provides for the establishment, management and maintenance by the Commission of an EU SoHO platform to facilitate exchange of information concerning SoHO activities in the Union. This platform would support activities provided for under other chapters of that Regulation, including:

- a) registration of entities and possible further authorization for preparation, import, establishments. Publication of registration/authorisation status;
- b) activity data reporting;
- c) vigilance reporting of serious adverse occurrences, and rapid alerts;

- d) traceability and coding;
- e) publication of technical guidelines;
- f) publication of assigned authorities, and information exchange between authorities across the Union;
- g) publication of guidance, training materials and Union-level advice provided by the SoHO Coordination Board.

The SoHO digital platform would significantly facilitate exchange, management, and consolidation of data. It will consequently also allow to prepare and publish reports, at national level as well as at Union level. Interoperability with relevant other Union-level digital initiatives, such as the European Health Data Space will be important to consider.

The objective of the action is to be ready in due time for application of the proposed SoHO Regulation. The scope of the action is the development of the first version of the EU SoHO platform, covering at least the “Minimum Viable Product”, defined as the proposed legal requirements of the SoHO regulation, and extra necessary features that will have been clarified by the analysis work of 2023.

The key activities include the development of several functional capabilities required to support the SoHO digital platform and the interoperability with other information systems, such as the Rapid Alert system for human Tissues and Cells (RATC) and the EU Coding Platform or the Early Warning and Response System (EWRS):

- a) registration capability: this capability is among others needed to support several provisions like entity registration and authorisation of preparation processes;
- b) publication: this capability is needed among others to publish a list of registered entities, authorized establishments, technical standards, contact details;
- c) reporting and monitoring: this capability will among others allow to report, collect and monitor activity data as well as vigilance data;
- d) notifications and alerts: this capability will allow among others the managing of safety alerts (serious adverse occurrences) as well as supply alerts;
- e) collaborative space: this capability increases among others, the efficiency of work in each of the national authorities, allowing them to quickly retrieve contacts and expertise in peer authorities.

This action supports the implementation of the future legislative framework for Substances of Human Origin and it implements the EU4Health Programme’s general objective of strengthening health system, (Article 3, point(d), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service under existing or new framework contract.

Indicative budget for this thematic area: EUR 2 822 000

Implementation by: DG SANTE

4.4 IMPLEMENTATION OF CROSS-BORDER HEALTHCARE DIRECTIVE

HS-p-24-61 Make full use of the current legal framework for cross-border healthcare: review the applicability of existing Union legislation to telemedicine services

Directive 2011/24/EU¹³⁹ on the application of patients' rights in cross-border healthcare providing for patients' rights was last evaluated in 2022.

The review of the applicability of existing Union legislation to telemedicine services, which was carried out in 2012, is listed as one of the follow-up actions to enhance the implementation of the Directive in the Action Plan of the Evaluation Report.

Since the COVID-19 pandemic, the use of telemedicine has increased substantially; the review is needed to guide further actions which would support a better application of telemedicine in the Union and its Member States.

The aim of the revision is to check whether the current Union legislation on telemedicine service is still fit for purpose and to identify possible gaps in the legislation. The action will build on the work carried out in 2012 and additionally will map the applicable legislative frameworks in Member States and EEA countries regarding telemedicine.

The study would deliver an analysis of the current Union legislation and its applicability, taken into consideration the changes occurred with the COVID-19 pandemic and the increased use of telemedicine services. Moreover, the study will deliver an overview of the use of telemedicine in Member States and EEA countries. The results can be used effectively by DG SANTE and other DGs for assessing the potential need for legislative revision and support the implementation of telemedicine in Member States.

This action implements the EU4Health Programme's general objective to strengthen health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: request for service using the existing framework contract on Better Regulation.

Indicative budget for this thematic area: EUR 200 000

Implementation by: HaDEA

4.5 IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES

HS-p-24-62 Support to EUDAMED

The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new medical devices legislative framework. EUDAMED improves transparency and coordination of information regarding medical devices that are available on the Union market. This action will support the finalisation of development, improvement, and maintenance of the EUDAMED database. EUDAMED is one of the core elements of Regulation (EU) 2017/745¹⁴⁰

¹³⁹ 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](#)).

¹⁴⁰ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([OJ L 117, 5.5.2017, p. 1](#)).

(MDR) and Regulation (EU) 2017/746¹⁴¹ (IVDR). Its use by economic operators, competent authorities, sponsors of clinical investigations/performance studies and notified bodies is a legal obligation stemming from Regulations and it constitutes the spine of the implementation of the medical devices regulatory framework as it allows centralisation and efficient management of data on medical devices and *in vitro* diagnostic medical devices. It also serves to increase transparency through better access to information for the public. EUDAMED is now in an advanced stage of development and the WP 2024 is supporting the finalisation of its development. EUDAMED is structured around 6 interconnected modules: Actors registration, UDI/Devices registration, Notified Bodies and Certificates, Clinical Investigations and performance studies, Vigilance and post-market surveillance, Market Surveillance - with the first 3 already available for voluntary use.

The action will contribute to the finalisation and maintenance of the EUDAMED database, by:

- a) supporting the finalisation of the two very complex modules dedicated to ‘clinical investigation and performance studies’ and ‘vigilance and post-market surveillance’, where a number of challenges have been identified, requiring appropriate technical solutions;
- b) fine-tuning of the first 3 modules already available or finalized (market surveillance) to ensure their smooth functioning once the system will become mandatory;
- c) functional specifications still to implement for the system that were agreed to be done after EUDAMED minimum viable product full functionality;
- d) maintenance, training and support for the system use.

This action supports the implementation of the legislative framework for medical devices, and 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 (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangement, other framework service contract, open call for service contract or negotiated procedure for service contract.

Indicative budget for this thematic area: EUR 4 700 000

Implementation by: HaDEA/DG SANTE

HS-p-24-64 Horizon scanning for medical devices

In addition to the anticipated changes in healthcare demand, the medical devices field and market are evolving rapidly. The aim of horizon scanning in the area of medical devices is to monitor the development of new medical technologies in order to detect those bringing major benefits, as well as those with potential disruptive effects on the implementation of Regulations (EU) 2017/745 and 2017/746 on medical devices and *in vitro* diagnostic medical devices resulting in impacts on national health systems. Horizon scanning allows regulators to stay informed about new and emerging technologies, innovations, and trends in healthcare, allowing them to make timely and evidence-based decisions to avoid future threats and prepare for

¹⁴¹ 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](#)).

opportunities which may impact their activities, and the organisation and sustainability of health systems across the Union.

This action supports the work of the Medical Devices Coordination Group (MDCG) on issues related to application of new and emerging technologies to medical devices under Regulation (EU) 2017/745 and *in vitro* diagnostic medical device under Regulation (EU) 2017/746. The requirement for establishing a horizon scanning system for medical technologies is also laid down in the terms of reference of the MDCG New Technologies sub-group. The Horizon Scanning system will provide key input to regulators and all stakeholders and prepare the analysis of regulatory and market access challenges faced by certain technologies. In addition, it will provide key input to the development of proposals for guidance and common specifications in the field of medical devices as referred to in Article 9 of Regulation (EU) 2017/745 /Article 9 of Regulation (EU) 2017/746.

The objective of this action is to support the MDCG' horizon scanning work, aiming to systematically and continuously identify opportunities, risks or other features related to new and emerging technologies which may challenge the Union regulatory system on medical devices and *in vitro* diagnostic medical devices. This is of pertinence as these features have an impact on patient safety or public health, on the existing legal framework (qualification/classification/clinical/compliance), and on what regulators or notified bodies will have to assess.

It should be investigated which types of medical devices covered by MDR and IVDR are expected to emerge in the next 3 to 10 years (depending on the type of technology) and may have a potential major impact on the organisation and sustainability of health systems at national and Union level, especially on the regulatory system for medical devices and *in vitro* diagnostic medical devices.

In carrying out the action, technologies in various stages of development should be considered, and signals, trends and factors related to these technologies should undergo a high-level impact analysis.

The action should consist of:

- a) mapping the needs of the Member States, taking into account already existing national and international horizon scanning activities;
- b) adapting a search methodology building upon the already existing one in the MDCG New Technologies subgroup: defining the methodology for picking up on signals and trends to be detected, identifying the data sources necessary to carry out horizon scanning, defining a search strategy, defining selection and prioritisation criteria (e.g., degree of novelty, market maturity, potential new opportunities/risks) in order to establish a final list of new emerging technologies and their potential impacts;
- c) providing an IT tool, based on AI where possible, which would continuously collect data to detect signals and trends;
- d) in depth analysis of the medical devices selected and prioritised and provide predictions on their development (e.g., stage of development, regulatory status) and their short/long term potential impacts on the Union regulatory system (and national health systems).

In carrying out the action, there should be close collaboration with the Commission and the MDCG New Technologies sub-group.

The action should provide:

- a) a clear methodology to identify new medical devices within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with potential high impact on the Union's regulatory system concerning medical devices and *in vitro* diagnostic medical devices (and also on the organisation and sustainability of health systems);
- b) an initial list of new emerging technologies within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and their potential impacts, outlining the categories of devices where innovation may bring important benefits and/or risks;
- c) an IT tool, based on AI where possible, which continuously collects data and information regarding innovative developments in the field and detects signals and trends, according to the established methodology;
- d) an in-depth analysis of a selection of new emerging technologies within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and their short/long term potential impacts on the regulatory framework. In particular, it should be capable of identifying technologies which may struggle with meeting the existing regulatory requirements and provide a basis of the issues faced by those technologies;
- e) a list of experts and their field of expertise, who could provide input to the Commission and MDCG on new emerging technologies selected for an in depth analysis;
- f) following selection of areas and technologies requiring in depth analysis by the MDCG New Technologies subgroup, preparation of reports assessing the opportunities or challenges identified providing regulatory recommendations for mitigating the challenges or harnessing the opportunities identified.

These deliverables will support the work of the MDCG and are essential to ensure the application of the requirements on new and emerging technologies to medical devices under Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices under Regulation (EU) 2017/746.

This action supports the policy priority to support the implementation of the Regulations on medical devices and *in vitro* diagnostic medical devices and it implements the EU4Health Programme's general objective of, strengthening Health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (h) and (i), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tender for a service contract.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

HS-p-24-65 Studies supporting the evaluation of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR)

Medical devices and *in vitro* diagnostic medical devices (IVDs) have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease. Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* medical devices were adopted in 2017 with the aim to increase patient safety throughout the Union, whilst supporting innovation. As the capacity of notified bodies and preparedness of manufacturers remains insufficient until today to perform the activities required of them, the transition periods of these Regulations have been extended through amending Regulations. The Commission has been putting in place various actions to support the transition and to avoid shortage of medical devices needed for health systems and patients. In addition, also structural challenges that have

become evident in the regulatory framework would need to be addressed to ensure that healthcare professionals and patients have access to the devices needed for a high level of patient care, including innovative technologies. Those challenges include issues related to orphan devices, SME's access to notified bodies, length, and cost of conformity assessment procedures etc. In accordance with Article 121 of Regulation (EU) 2017/745 and Article 111 of Regulation (EU) 2017/746, by May 2027 the Commission is required to assess the application of the two Regulations and to produce an evaluation report on the progress towards the achievement of the Regulations' objectives, including an assessment of the resources required to implement the Regulations.

This action aims to support the Commission to carry out the assessment of the application of the Regulations, the related public consultation, and to draw up the evaluation report. The activities under this action should build on the outcomes of other EU-funded actions, including the study on regulatory governance and innovation in the field of medical devices and the study supporting the monitoring of availability of medical devices on the Union market (both funded under the EU4Health work programme 2022).

This action supports the implementation of the legislative framework for medical devices, and 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, (Article 3, points (c) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: request for service using the framework contract on Better Regulation, other framework service contract, open call for tender for service contract or negotiated procedure for service contract.

Indicative budget for this thematic area: EUR 400 000

Implementation by: HaDEA/SANTE

HS-p-24-66 Translation of medical devices and *in vitro* diagnostics nomenclature

To ensure the harmonised application of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by the Regulations to use that nomenclature. At European level, agreed upon nomenclature on medical devices is accessible in European Medical Device Nomenclature (EMDN) database in only a limited number of languages, which restricts its use by all stakeholders. The EMDN, together with the Adverse Event Terminology, aim at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, EMDN is utilised by manufacturers for the registration of medical devices and *in vitro* diagnostics in EUDAMED, where it will be associated to each Unique Device Identifier (UDI). It is intended to support all actors in their activities under the MDR/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 Adverse Event Terminology is essential for vigilance activities and is mainly used by competent authorities and manufacturers. Using the correct nomenclature has effects on both the European level and international level for registration, data analysis and communicating adverse events of medical devices and *in vitro* diagnostics. So far, EMDN nomenclature exists in English, French and Italian, as the Medical Device Coordination Group (MDCG) nomenclature subgroup has taken this burdensome work upon them, relying on the commitment of national

competent authorities. The Adverse Event Terminology is available only in English, as provided by the International Medical Device Regulators Forum (IMDRF). Due to the importance of this work to ensure a smooth functioning of the regulatory processes put in place by the MDR/IVDR and the limited availability of resources and expertise in national authorities to carry out this work, a dedicated action is necessary.

This action aims at facilitating the use of harmonised nomenclature on medical devices and *in vitro* diagnostics by all stakeholders by making the nomenclature available in all official languages of the Union. The activities under this action include the validation and harmonisation (e.g., ensuring the same terms are consistently used across the terms, correct review and syntax harmonisation of the already existing translated versions of the European Medical Device Nomenclature in all official languages of the Union. The Adverse Event Terminology, primary translations will need to be translated in all official languages of the Union, except English in which it already exists. Specialised expertise in medical device terminology is necessary to conduct both tasks. Resulting terminology will be in a machine-readable format. The content of both the European Medical Device Nomenclature and the Adverse Event Terminology in all EU official languages will be made available for public use by making sure it is available for import into the EU's database for medical devices (EUDAMED) and the EMDN platform.

This action supports the implementation of the legislative framework for medical devices and 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 (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (g), (h), (i) and (j), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tender for a service contract.

Indicative budget for this thematic area: EUR 800 000

Implementation by: HaDEA

HS-p-24-67 Support for guidance documents in the field of medical devices and *in vitro* diagnostics

In an effort to support the implementation of Regulations (EU) 2017/745 and 2017/746, the Medical Device Coordination Group (MDCG) has developed over 100 guidance/Q&A documents since the Regulations have come into force. The main objective of MDCG guidance is to assist economic operators, notified bodies and competent authorities to apply the legal requirements in a harmonised way, providing possible solutions endorsed by the MDCG (see MDCG 2022-14, action point no. 11). It is essential that guidance documents are kept up to date and to make sure that they still meet the pursued objective, i.e., to provide clear and useful assistance and clarification regarding the relevant legal requirements.

The aim of this action is to ensure the availability of clear and useful guidance for economic operators, notified bodies and competent authorities operating in the medical device field.

The action will include the analysis of existing MDCG guidance documents whether they are still up-to-date and how they meet the needs of manufacturers, other economic operators, notified bodies and competent authorities.

This activity should have a particular focus on SMEs, as these often face difficulties in meeting the administrative and financial burden that the regulatory framework of the MDR/IVDR

imposes. It should make proposals to the MDCG on possible changes to existing MDCG guidance documents, based on the aforementioned analysis.

This action will contribute to the work of the Medical Device Coordination Group.

This action is expected to result in a more harmonised implementation of various processes laid out in the MDR and IVDR to ensure a predictable and reliable regulatory framework that supports patient safety and innovation in the medical device and *in vitro* diagnostics sector in the Union.

This action supports the policy priority to support the implementation of the Regulations on medical devices and *in vitro* diagnostic medical devices and 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, (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c), (h) and (i), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tenders for a service contract.

Indicative budget for this thematic area: EUR 250 000

Implementation by: HaDEA

HS-p-24-100 Support to the technical secretariat for Notified Bodies Coordination Group (NBCG-Med)

To secure smooth implementation of sectorial legislation, the Commission provides support to the activities of notified bodies established under sectorial legislation (including Directive 2006/42/EC;¹⁴²; Directive 2014/30/EU¹⁴³). Considering the challenges that notified bodies are facing in the implementation of the Medical Device Framework, strengthening such support is essential to contribute to a smoother implementation of Regulations (EU) 2017/745 and 2017/746 of the European Parliament and of the Council.

This action has the objectives to:

- a) support the technical secretariat to help the drafting of technical documents for the implementation of the MDR/IVDR;
- b) support coordination among notified bodies to carry out specific activities necessary for the implementation of the MDR/IVDR.

Activities under this action will consist in providing services to NBCG-Med and assisting the Chairpersons of the NBCG-Med in carrying out technical related duties. Specific tasks include the coordination and scientific support to the NBCG-Med and its subgroups, the preparation and follow up of meetings, and communication activities.

This action aims to improve the capacity of notified bodies in delivering essential technical documentation necessary for the smooth implementation of the MDR/IVDR.

This action supports the implementation of the legislative framework for medical devices, and it implements the EU4Health Programme's general objective of improving the availability,

¹⁴² Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC ([OJ L 157, 9.6.2006, p. 24](#)).

¹⁴³ Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility. ([OJ 96, 29.3.2014, p. 79](#)).

accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service contract using an existing or new framework contract.

Indicative budget for this thematic area: EUR 450 000

Implementation by: HaDEA

HS-p-24-68 Joint assessment of notified bodies

This action supports the implementation of the legislative framework for medical devices, and 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 (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangements.

Indicative budget for this thematic area: EUR 150 000

Implementation by: DG SANTE

HS-p-24-101 Support to the peer review and exchange of experience between authorities responsible for notified bodies

Availability of safe and performant medical devices and *in vitro* diagnostics is essential in the diagnosis and treatment of European patients. In 2017, Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) were adopted to safeguard patient safety whilst supporting innovation in the sector.

Under these Regulations, actors of the medical devices/*in vitro* diagnostics field have a variety of actions to perform. For instance, national competent authorities designate notified bodies to perform third-party conformity assessment activities. As part of their role to designate notified bodies, the national authorities responsible for notified bodies must participate in peer-review activities to exchange experience and coordination of administrative practice between authorities (Article 35 MDR and Article 31 IVDR).

The process to conduct peer review activities is still currently under development, with a taskforce in the Medical Device Coordination Group looking to develop a sound mechanism for conducting peer reviews. However, a survey of national competent authorities has revealed disparities in preferences on how to set up the mechanism. It was decided that a pilot project would be started to further develop the peer review process, address concerns raised by national competent authorities, raise awareness of pitfalls to be avoided, determine the need and extent of supporting documents to be created and clarify the possibilities of different peer review scenarios within the currently available capacity. This pilot project is expected to run until May 2024.

After this date, it will be essential to ensure a continuity of the established activities following the progress that has been achieved through the pilot by means of an EU4Health action to

support the organisation of the peer review process in line with the relevant provisions in the MDR/IVDR (Article 35 MDR and Article 31 IVDR).

The action aims to support national competent authorities in the peer review activities and exchanging of experience between competent authorities responsible for notified bodies. The action will provide financial support to national competent authorities responsible for notified bodies to conduct peer review activities, including the provision of interpreters during the peer-review activities, as necessary.

The action is expected to result in a more harmonised implementation of the peer review process laid out in the MDR and IVDR to ensure a predictable and reliable regulatory framework that supports patient safety and innovation in the medical device and in vitro diagnostics sector in the Union.

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

Indicative type of contracts/supply: administrative arrangements.

Indicative budget for this thematic area: EUR 200 000

Implementation by: HaDEA / DG SANTE

HS-p-24-103 Programme of Continuous Learning within a European Health Union Professional Network

Europe benefits from diverse stakeholders active in capacity-building for health policy development and implementation in Europe, delivering high-quality training and professional education. These capacity-building entities target a range of policy-relevant expertise and include specialised training programmes such as health law, health economics, and public health. Altogether, they provide a wide coverage of the relevant knowledge including a research focus through academic collaboration, but this remains scattered, and their several decades of excellent output is not fully harnessed. Therefore, there is a need to develop a network of Union health policy makers that share a profound understanding of the Union's Health policy and instruments, and a solid basis of interpersonal and professional trust.

This action will develop a state-of-the art capacity-building programme building on existing training capacities and provide a unique programme of continued professional development for European Health Policy professionals.

The aim of the action is to build, through a continuous capacity building programme, a robust and growing Union network of peers from Ministries of Health and relevant departments across national administrations who can be contacted in case of questions on Union health policies, thereby actively contributing to Union policies and programmes and effectively using Union instruments. The network will include a built-in multiplier mechanism to facilitate the transfer of knowledge and expertise to a broad range of actors.

Each year, a cohort of 54 mid-career professionals (two per Member State) from Member States Ministries of Health or other relevant administrations will be enrolled in a one-year supervised learning by doing training programme. The network of professionals will not only include the cohort of participants, but also the graduated alumni, their supervisors, training facilitators and stakeholders, a permanent and growing community who collaborate and contribute to build a stronger European Health Union.

Activities will include face-to-face technical training modules on Union public health policies, face-to-face and online workshops, exchange of practices, implementation of projects, an annual conference, and an annual collaborating platform.

The expected result is a growing network of well-trained professionals who have a comprehensive view of the European health agenda share a solid professional trust base, and the ability to connect swiftly and contribute to resolve outstanding Union and/or national health policy matters.

The impact is having a broad and trusted platform for good-faith discussions on better policies to promote health for all peoples of the EU.

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

Indicative type of contracts/supply: open call for tender for a new framework contract; service contract.

Indicative budget for this thematic area: EUR 810 000

Implementation by: HaDEA / DG SANTE

5. DIGITAL (DI)

DI-p-24-71 Communication and information activities to support the rollout and use of the planned European Health Data Space (EHDS) and related services

The proposed European Health Data Space ('EHDS') is an overarching initiative in health, one of the key pillars of European Health Union, and involves a large number of stakeholders. Engagement and communication activities are a key aspect of building trust across the communities participating in the EHDS. Key stakeholders include, among others, patient and healthcare providers associations, the general public, healthcare providers, healthcare professionals, Member States' authorities and regulators, academia and research communities, EHR systems manufacturers and health IT providers and industry.

The objective of this action is to reinforce communication and stakeholder engagement activities in order to advance the rollout of the EHDS. More specifically, this action also aims at increasing the visibility of the EHDS services, such as MyHealth@EU, in order to increase their use and to promote digital inclusion. The scope of the action is primary and secondary uses of health data in the context of the EHDS.

Such communication and information activities should be achieved through appropriate actions, such as distribution of promotional videos, specialised events and workshops, or communication campaigns, adapting the messages to stakeholder needs, e.g., needs of health professionals on EHDS services and infrastructures such as MyHealth@EU, or needs of the research community on HealthData@EU.

Activities in scope of this action include:

- a) advice on the design and planning of integrated communication and information activities, both for communication campaigns and single activities, addressing the needs of stakeholders in the EHDS;
- b) preparation of communication and information strategies for the implementation of the EHDS and for raising awareness of the EHDS services and infrastructures;
- c) analysis, monitoring and communication of the most relevant outputs and milestones related to the EHDS;
- d) preparation of the necessary materials for engaging and communicating with stakeholders on the EHDS, e.g., development of media products, design and illustration, production of audio-visual and multimedia contents;
- e) definition, planning, coordination and implementation of communication and information activities, e.g., communication campaigns through appropriate channels (online or offline), digital outreach activities (websites, platforms, and other digital applications), dissemination, events and conferences, translation services.

These activities are expected to ensure that key stakeholders are aware and well informed of the EHDS services and infrastructures and ready to engage in the further rollout of the EHDS. This is also expected to foster inclusion of stakeholders in the implementation of the EHDS.

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

Indicative type of contracts/supply: open call for tenders or a request for service under a framework contract (if available).

Indicative budget for this thematic area: EUR 1 600 000

Implementation by: HaDEA

DI-p-24-72 Support centre for the European Electronic Health Record exchange Format (EEHRxF) and for the interoperability and security of electronic health record systems

Several Union initiatives have contributed to the development and adoption of the technical specifications for the European Electronic Health Record exchange Format (EEHRxF), including the MyHealth@EU infrastructure and the X-eHealth and XpanDH projects. In addition, the joint action on primary use of health data from the 2022 work programme of EU4Health aims at providing recommendations for a formal description of the format.

The EEHRxF needs to be further defined into implementable technical specifications. There is a need to support the implementation of these technical specifications by as many stakeholders as possible. Relevant stakeholders ('implementers') include EHR systems manufacturers, health institutions and healthcare providers, among others.

The objective of this action is to set up and operate a support centre to advance the adoption of the EEHRxF and the key aspects such as the interoperability and security of EHR systems towards the implementation of the EHDS. The support centre will provide services to implementers intending to ensure compatibility of their systems with the EHDS requirements. This action will support preparedness of the relevant stakeholders for data exchange in the context of the EHDS.

The scope of the EEHRxF support centre includes the creation and support of a community of practice focusing on the adoption of the EEHRxF and EHDS requirements. This work will be carried out in complementarity with other initiatives focusing on the EEHRxF and the EHDS.

The specific activities covered by this action include:

- a) supporting the creation, stimulation and moderation of an EEHRxF community of practice (e.g., with workshops, policy briefs, surveys, analysis materials, knowledge sharing activities), ensuring the appropriate involvement of the users of the EEHRxF; and experts in patient information exchange;
- b) consolidating requirements and specifications (e.g., on interoperability and security) for EHR systems, as well as checklists and other tools, and provide them online to guide and assist implementers;
- c) conducting analysis and monitoring work as well as support actions to advance the implementation of the EEHRxF, the improvement of interoperability and security of EHR systems, and the improvement of data quality, including for secondary use;
- d) providing and maintaining tools and resources online to support the implementation of the EEHRxF and the improvement of other aspects of interoperability and security (e.g., tools and resources for implementers for health data structuring, data quality improvement, conversion, testing or validation, classification of EHR systems);
- e) support implementers and other relevant stakeholders on the adoption EEHRxF and best practices for interoperability, security, and secondary uses.

The expected results of this action will be the creation of a one-stop-shop that will accelerate actions towards the development and adoption of the EEHRxF and the alignment of EHR systems with the planned EHDS, in particular its interoperability and security aspects. The provision of services and tools to support and accelerate the implementation of EEHRxF and other aspects of the planned EHDS will lead to an increase of interoperability and security in health and a faster and more efficient rollout of the EHDS.

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

Indicative type of contracts/supply: open call for tenders or a request for service under a framework contract (if available).

Indicative budget for this thematic area: EUR 4 500 000

Implementation by: DG SANTE /HaDEA

DI-p-24-73 Support to key stakeholders and HealthData@EU participants in scope of the proposed European Health Data Space

The proposal for a Regulation on the European Parliament and of the Council on the European Health Data Space ('EHDS')¹⁴⁴ lays the legal foundations to facilitate the secondary use of health data and the setup of a dedicated cross-border IT infrastructure named HealthData@EU. In preparation to implement the EHDS in the area of secondary use of health data, there is a need to support key stakeholders to comply with the EHDS requirements and technical specifications while supporting their collaboration in the rollout and operations of HealthData@EU.

Key stakeholders include, among others, the community of practice of health data access bodies, health data research infrastructures and other relevant data sharing infrastructures health data holders, relevant Union bodies, and relevant third parties, e.g., patient representatives, national statistical offices involved in HealthData@EU and in the EHDS.

Additionally, this action will also support the setup and running of various secondary use governance bodies in the context of the EHDS.

This action aims at supporting key stakeholders to provide, process and reuse health data in the scope of EHDS. This action will promote continuous engagement with key stakeholders.

It will also support the organisation, functioning and governance of HealthData@EU IT infrastructure.

The main activities of this action include:

- a) supporting the creation and operation of communities of practice bringing together the main stakeholders in secondary uses of health data, including those involved in the HealthData@EU IT infrastructure;
- b) supporting cooperation and knowledge sharing between key stakeholders in secondary uses of health data, and provide digital tools for collaborative work;
- c) support the implementation of the governance procedures of the HealthData@EU IT infrastructure;
- d) providing the secretariat to communities and groups involved in secondary use of health data (e.g., by organising recurring meetings, workshops and helpdesk activities);
- e) monitoring and evaluating progress made by stakeholders on secondary use of health data in scope of the EHDS (e.g., by collecting and reviewing reports from health data access bodies and HealthData@EU participants);

¹⁴⁴ Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. [COM \(2020\)197](#) Final

- f) supporting compliance with requirements and the adoption of technical specifications for the secondary use of health data.

This action is expected to strengthen cooperation between key stakeholders and accelerate their readiness for provision, processing and reuse of health data and ultimately contribute to the secondary use of health data in the EHDS. This action will complement, and support further other actions launched in previous work programmes of EU4Health.

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

Indicative type of contracts/supply: open call for tenders or a request for service under a framework contract (if available).

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: HaDEA

DI-p-24-74.1 Operations and further development of HealthData@EU (central services)

HealthData@EU aims to connect health data access bodies, relevant Union bodies and health data sharing infrastructures to enable the reuse of health data in the context of the proposed European Health Data Space (EHDS). The proposal for a Regulation on a European Health Data Space¹⁴⁵ provides for this HealthData@EU infrastructure. A pilot was launched in 2022 to develop and test the HealthData@EU infrastructure, with a view to the scale-up of this infrastructure after its completion.

The objective of this action is to reinforce and develop further the central services provided by the Commission during the pilot and for the large-scale deployment of HealthData@EU, including the expansion of the capacity of central services and the adaptation of the piloted infrastructure to the latest developments. This will contribute to an efficient operation of the central services of EHDS infrastructures.

This action will build on and take further the HealthData@EU pilot and the previous activities funded under the EU4Health Programme to develop the central services of HealthData@EU and to prepare the ground for the secondary uses of health data within the EHDS, such as relevant joint actions on secondary uses of health data (e.g., joint action TEHDaS)¹⁴⁶ or the direct grants for setting up health data access bodies.

The scope of this action is the preparations for the large-scale deployment HealthData@EU infrastructure both during its piloting and after. The specific activities in scope of this action include:

- a) analysis, design, development and deployment of the central services provided by the Commission for HealthData@EU, including, for example, technical infrastructures, software, hosting, reference implementations (e.g., secure processing environments) and governance elements, and their adaptations and expansions;
- b) operations of the common technical infrastructure for HealthData@EU.

The activities covered by this action are expected to:

¹⁴⁵ Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. [COM \(2020\)197](#) Final.

¹⁴⁶ Joint Action Towards the European Health Data Space ([TEHDAS](#))

- a) ensure the development, deployment and operation of the central services of the Union-wide digital infrastructure for secondary uses of health data (HealthData@EU);
- b) enable the onboarding of a large number of participants in the infrastructure towards achieving Union-wide coverage;
- c) reduce the costs and burden of the lawful access of researchers and innovators, policy makers and regulators to electronic health data;
- d) enable and facilitate the reuse of electronic health data from multiple countries in data-driven initiatives that require Union-wide data to attain meaningful, and otherwise not possible, insights, through a common Union infrastructure (HealthData@EU).

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

Indicative type of contracts/supply: service, administrative arrangement, co-delegation to DG DIGIT and existing or new framework contract.

Indicative budget for this thematic area: EUR 1 150 000

Implementation by: DG SANTE

DI-p-24-74.2 Compliance checks for infrastructures of the proposed European Health Data Space

As part of the European Health Data Space (EHDS) initiative, the Commission is developing the central services for HealthData@EU, alongside with the central services it already operates for MyHealth@EU. As part of the central services of MyHealth@EU, the Commission conducts compliance checks and/or audits on the participants in the infrastructure (National Contact Points for eHealth). With the development of HealthData@EU, it is expected that authorised participants will be subject to compliance checks and/or audits.

The objective of this action is to conduct and support compliance checking and/or auditing for cross-border infrastructures in the EHDS. In scope for this action are HealthData@EU and MyHealth@EU.

The specific activities in scope of this action include:

- a) the development and updating of compliance check and/or audit frameworks;
- b) the organisation of compliance checks and/or audit teams, as necessary, and the management of preparatory, follow-up and support activities related to compliance checks and/or audits;
- c) planning and execution of compliance checks and/or audits;
- d) supporting relevant stakeholders during the compliance checks and/or audits.

The activities covered by this action are expected to ensure compliance of the participants in HealthData@EU and/or MyHealth@EU with the applicable rules and frameworks. The audits/compliance checks will identify findings that may pose risks to confidentiality, integrity or availability of the HealthData@EU and/or MyHealth@EU services provided. This will increase the trust of participants and other stakeholders in these infrastructures and in the EHDS as a whole. The participants in these audits and/or compliance checks (e.g., National Contact Points for eHealth or participants in HealthData@EU) may use the outcomes of the audits and/or compliance checks as input to the applications to start or to continue the provision of cross-border services in the scope of HealthData@EU and/or MyHealth@EU.

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

Indicative type of contracts/supply: open call for tenders or a request for service under a framework contract (if available).

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: HaDEA

6. RECURRENT, HORIZONTAL, IT AND COMMUNICATION ACTIVITIES

The actions have as objectives the organisation of events and meetings through covering expert expenses, including special indemnities, in particular in relation to participation in steering groups and expert panels, 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 support to the Health Policy Platform to build up good collaboration and communication channels with its health stakeholders and health networks, the support in studies, analysis, impact assessments and evaluations of health-related legislation. These activities will also cover 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. These activities will also cover the participation of Union delegates to the International Medical Device Regulatory Forum (IMDRF) as well as aid in the evaluation of the European Reference Networks and the work on rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources.

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 and translation service.

In line with the Commission's ambition to build a European Health Union for people and the Commission's One Health approach, communication in 2024 will focus on key political priorities including the European Health Union, Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, vaccination, AMR and the Global Health Strategy.

Moreover, in accordance with Article 26 of Regulation (EU) 2021/522 and as announced in the Communication to the Commission on 'Corporate Communication action in 2024-2027 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 objectives referred to in Articles 3 and 4 Regulation (EU) 2021/522 will be supported.

This action also covers the experts' evaluation for proposals received by HaDEA, study on quantitative methodology for health impact assessment, studies and experts and technical support for the implementation of Regulations (EU) 2017/745 and 2017/746, other Union legislation on health and policies related to COVID-19.

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

These actions implement the EU4Health Programme's overall objective to improve human health throughout the Union and to ensure a high level of protection of human health in all

Union policies and activities and all general objective referred to in Article 3 (a) to (d), of Regulation (EU) 2021/522 through the specific objectives defined in Article 4, points (a) to (j) of Regulation (EU) 2021/522.

The expected results are:

- a) **for activities of Health Policy Platform (HPP):** the Virtual Platform is an IT-infrastructure contributing to: the exchange of communication between DG SANTE and stakeholders (via the “Agora”); the development of joint statements by stakeholders on specific issues (through temporary “thematic networks”); the preparation of collaborative documents supporting specific policy objectives of the Commission and Member States; discussion on selected topics through regular webinars; support the communication of Commission expert and stakeholder groups.
- b) **for activities of scientific committees, functioning of expert groups, meetings and technical assistance:** the development the scientific evidence base opinions/documents required for drafting legislation that has direct impact on the lives of the citizens, on the efficiency and resilience of the health systems and the good functioning of the internal market. Reviewing and evaluating available relevant scientific data to derive conclusions and assessing potential risks;
- c) **for communication:** production of media and communication assets and their targeted dissemination to targeted sections of the media, general public, a range of stakeholders and multipliers over a wide range of channels will trigger broad coverage and higher awareness of Union health policies and HERA’s corporate communication activities; participation to EXPO 2025 Osaka, Kansai, Japan - promoting themes such as protection of lives including in relation to climate change related health risks, public health improvement, biosimilars and new vaccines, etc. and showcase EU solutions and initiatives;
- d) **for IT:** provision of corporate technical services;
- e) **for evaluation:** improved capacities to carry out evaluations of existing legislation and/or legislative proposals and the evaluation of European Centre for disease prevention and control¹⁴⁷, as well as for the ERNs and work on rare diseases;
- f) **for expert and technical evaluation activities:** expertise and technical assistance and support in the field of public health, exploratory studies, evidence gathering, prospective analysis and foresight, policy analysis;
- g) **for stakeholder-related activities:** an enhanced Health Policy Platform and organisation of and participation in events; studies and evaluations, where relevant;
- h) **for implementation of the health legislative framework:** participation of experts in audits for the GMP and GDP joint audit programme, for the joint assessment of Notified Bodies, participation of Union delegates to the International Medical Device Regulatory Forum (IMDRF), Health Security Committee meetings under Regulation (EU) 2022/2371 on serious cross-border threats to health;
- i) **for Union representation to international fora:** participation of EU delegates at international level in the field of medical devices and in vitro diagnostics;
- j) **for the Global Health Strategy:** internal database and repository permanently mapping of all global health actions and funding streams of the institutions and Member States,

¹⁴⁷ Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 31, 6.12.2022, p.1).

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as well as comparison to targets for those actions with an external interactive tool to show the world actions undertaken in any given country or regions.

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

Indicative type of contracts/supply: service contract based on exiting framework contract, open procedures or competitive procedures with negotiation or competitive dialogue procedure, administrative arrangements, co-delegation with DG COMM, co-delegation with DG DIGIT, co-delegation with FPI.

Indicative budget for this thematic area: EUR 10 628 856

Implementation by: DG SANTE/HERA/HaDEA

C. OTHER ACTIONS AND EXPENDITURE

In 2024, the Commission intends to launch the following actions which contribute to one or several strands.

Membership fees to International Organisations and regulatory bodies

HS-o-24-69 Annual membership fee to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)¹⁴⁸ 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.

HS-o-24-70 Annual contribution to the International Pharmaceutical Regulators Programme¹⁴⁹ (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-24-49 Annual contribution to the European Observatory on Health Systems and Policies Partnership

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

DP-o-24-23 Technical implementation of the Tobacco Products Directive

Directive 2014/40/EU lays down a number of provisions concerning the ingredients and emissions of tobacco products and related products including safety and quality requirements for nicotine-containing e-cigarettes. It requires prior notification of novel tobacco products and prohibits cigarettes and roll-your-own tobacco with characterising flavours (e.g., menthol). A need for further technical and scientific input for the implementation of the Directive 2014/40/EU have has been jointly identified by the relevant services of DG SANTE and JRC as the basis for continuation of the mutual administrative arrangement in this area.

It should further support the implementation of Directive 2014/40/EU and its monitoring through technical expertise and laboratory capacity (in particular to analyse the ingredients of tobacco products and e-cigarettes) of JRC. The research requirements for these products include

¹⁴⁸ 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', COM(2015)7256 final.

¹⁴⁹ Commission Decision of 18 May 2021 on the participation of the Commission as a Member in the 'International Pharmaceutical Regulators Programme', COM(2021) 3312 final.

determining their composition and nicotine content, emissions, and assessing whether they contain particular ingredients such as flavouring substances.

The activities will include:

- a) contribution to the harmonisation and standardisation of testing protocols on ingredients and emissions operation;
- b) analysis of substances contained in heated tobacco products and in their emissions;
- c) support JATC-2 on methods for the chemical testing of tobacco products;
- d) scientific input for assessment of characterising flavours.

This action should further support the application of Directive 2014/40/EU and monitoring through technical expertise and laboratory capacity (in particular to analyse the ingredients of tobacco products and e-cigarettes) of the JRC. The research requirements for these products include determining their composition and nicotine content, emissions, and assessing whether they contain particular ingredients such as flavouring substances.

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

Indicative type of contracts/ supply: administrative arrangement with JRC.

Indicative budget for this thematic area: EUR 100 000

Implementation by: HaDEA / DG SANTE

DP-o-24-31 Reducing the burden of disease on public health

In 2022, the Commission presented the 'Healthier together' – EU Non-Communicable Diseases Initiative (EU NCD Initiative) to support Member States in identifying and implementing effective policies and actions to reduce the burden of major non-communicable diseases (NCDs) and improve citizens' health.

The EU NCD Initiative covers the period 2022-2027 and includes five strands: 1) a horizontal strand on shared health determinants, focusing on population-level health promotion and disease prevention of NCDs (complementing the actions of Europe's Beating Cancer Plan); 2) diabetes; 3) cardiovascular diseases; 4) chronic respiratory diseases; and 5) mental health and neurological disorders.

Financial support under the EU4Health work programmes 2022 and 2023 has been provided to support the implementation of actions identified by the Member States under the above-mentioned strands.

After the first wave of support to the Member States in the context of the EU NCD Initiative, it is important to adjust and improve its functioning of the initiative by further refining the identification of best practices, innovative policies, and cost-effective approaches that can deliver population impact, identifying challenges common to groups of Member States to team up and cooperate closely on implementation of actions addressing common challenges, and addressing specific areas to better support vulnerable populations and/or uncovered areas.

NCDs other than the ones covered by these strands may also be addressed through joint work and collaboration between the Member States. Such NCDs may include digestive diseases, kidney diseases, musculoskeletal disorders, substance use disorders, age-related disorders other

than dementia and approaches to tackle smoking and harm due to the use of alcohol and illicit drugs.

In Europe's Beating Cancer Plan, the Commission announced that it would put forward actions to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2040, compared to around 25% today. In 2023, the Commission intends to launch a revision of the 2009 Council Recommendation on smoke-free environments¹⁵⁰. Since 2009 there have been technological advancements and an increase in market shares of emerging tobacco products (such as e-cigarettes and heated tobacco products). In addition, the 2009 Council Recommendation on smoke-free environments include indoor and enclosed spaces in its scope but other public spaces such as certain outdoor spaces are only covered on a case-by-case basis. The key objective of the revision is to protect people in the Union from exposure to second-hand smoke and aerosols. It will address risks from emerging products or from exposure to second-hand smoke and aerosols in certain outdoor spaces.

The aim of this action is to reduce the burden of NCDs, and their risk factors, both at individual and population level, and to support the Member States in their efforts to meet the Sustainable Development Goals, in particular Goal 3, Target 3.4, as well as the NCDs targets of the WHO.

The aim of this action is to provide support for an individual approach to each Member State in their efforts to reduce the burden of disease.

The activities will include support for the activities of the Expert Group on Public Health (PHEG) in relation to health promotion and prevention of NCDs including tobacco, mental health and health determinants.

Specifically, the activities will include:

- a) knowledge generation and sharing for NCD prevention and management, quality assurance support for patient pathways, and support to health information systems and to fighting health inequalities (progressively with anticipatory and modelling capabilities);
- b) support to the development of knowledge and expertise on NCDs, including by providing mapping and analysis, and by supporting leveraging collaborative networks of excellence, contributing to raising the quality of prevention and care in the EU, coordinating and providing guidance and support to policy planning, monitoring and anticipation;
- c) collation and analysis of related inequalities and providing evidence-based approaches to NCD prevention, screening, diagnosis, treatment and care, all tailored, designed to support implementation by Member States;
- d) support to Member States and the Commission with technical work and assessments related to efforts to reduce NCD burden, tobacco control and promotion of mental health;
- e) knowledge generation and sharing on tobacco related risk factors such as the health risks and impacts related to the exposure to second-hand aerosols originating from emerging products such as electronic cigarettes and heated tobacco products.

Where relevant, the specific needs of vulnerable population groups such as Roma populations, displaced people from Ukraine and migrants/refugees will be addressed.

The expected results of this administrative arrangement include:

¹⁵⁰ Council recommendation of 30 November 2009 on smoke-free environments ([2009/C 296/02](#)). OJ C 296, 5.12.2009, p. 4.

- a) enhanced resilience and sustainability of the health systems in the Union with mapping, advice, guidance and assessment of policy, regulatory and technical measures related to reducing the burden of NCDs;
- b) development of knowledge and expertise on NCDs;
- c) mapping and analysis, and by supporting leveraging collaborative networks of excellence;
- d) guidelines and recommendations for prevention and control of NCDs and their risk factors;
- e) development of knowledge on risk factors related to tobacco such as the second-hand exposure to aerosols originating from emerging products such as electronic cigarettes and heated tobacco products.

This action implements the EU4Health Programme's general objectives of improving and fostering health in the Union and of strengthening health systems by improving their resilience and resource efficiency (Article 3, points (a) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (h), (i) and (j), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangement with JRC.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: DG SANTE/HaDEA

DP-o-24-32 Support to the European Environment Agency for the European Climate and Health Observatory

The European Climate and Health Observatory ('Observatory') is a partnership between the Commission, the European Environment Agency (EEA) and several other organisations. It contributes to the European Green Deal and the EU4Health vision for a healthier Union. It aims to support Europe in preparing for and adapting to the impacts of climate change on human health by providing access to relevant information and tools. It also fosters information exchange and cooperation between relevant international, European, national and non-governmental actors.

Launched in February 2021, the European Climate and Health Observatory allows policy- and decision-makers to visualise climate change-related health risks and it helps them to take action and respond to these risks. The Union's and Member States' national administrations, as well as sub-national authorities, can benefit from the pooling and exchanging of knowledge and solutions across borders, and from close collaboration and cooperation. The Observatory supports the policy making process through the development of knowledge, early warnings and predictions and practical responses related to the effects of climate change on public health. It furthermore supports adaptation plans and measures in Member States related to climate change and health and provides access to publications and reports, research and knowledge projects, guidance material and information portals related to climate and human health in Europe.

The European Climate and Health Observatory aims to:

- a) allow its users to monitor key climate-related health risks, impacts and adaptive responses through robust indicators;
- b) enable national and sub-national health policies and systems to integrate adaptation more systematically and consistently;
- c) enhance the capacity of public authorities to anticipate and prevent climate-related threats to health in a timely manner;

- d) empower the health community in Europe to become climate-literate and better integrated into adaptation decision-making processes;
- e) increase knowledge of evidence-based, efficient, effective and inclusive adaptation solutions and public health and healthcare interventions.

The activities of this action will result in:

- a) knowledge, data and insights in selected areas related to heat stress and climate-sensitive infectious diseases;
- b) insights on the effects of climate change on the water cycle and their impact on human health;
- c) guidance on heat health warning systems;
- d) recommendations for reducing the impacts of heat on people in home, work and public facility settings;
- e) advice and training programmes for health professionals and citizens on how to prevent and minimise impacts on climate on health.

This action implements the EU4Health Programme's general objective of strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service level agreement with EEA.

Indicative budget for this thematic area: EUR 400 000

Implementation by: DG SANTE

HS-o-24-102 Scientific, technical, and administrative support for EU Reference Laboratories and Expert Laboratories in the field of *in vitro* diagnostics and medical devices respectively

In 2017, the Union has updated its legislative framework for medical devices. Two new Regulations entered into force on 25 May 2017(??), one addressing medical devices (Regulation (EU) 2017/745) and one addressing *in vitro* diagnostics (Regulation (EU) 2017/746). This framework is central to fostering the development of safe, effective, and innovative medical devices and *in vitro* diagnostics, for the benefit of European patients, consumers, healthcare professionals and manufacturers.

As part of this regulatory framework for *in vitro* diagnostics established under Regulation (EU) 2017/746, the Commission is to set up EU reference laboratories (EURLs) (Article 100 of Regulation (EU) 2017/746) that carry out several tasks for high-risk diagnostics. Following a first call to designate EURLs in 8 scopes, several EURLs are expected to be designated in Q3 2023, however only in some of the 8 scopes. This work to designate EURLs was carried out by the Commission with the support of JRC, provided in the context of an already existing administrative arrangement that comes to an end in June 2024. However, the EURLs will have to be further supported beyond that date, as they will have to for instance harmonise their methods and put in place the necessary infrastructure to perform their tasks. To ensure the continuity of the support that the JRC has provided in the preparation and designation of the EURLs so far, it is essential that a new administrative arrangement is concluded as a continuation of the already existing one, to support the operationalisation of already designated

EURLs and the preparation of any subsequent calls to designate EURLs in remaining/other scopes in the future.

Under Regulation (EU) 2017/745, the Commission may designate expert laboratories based on their expertise in (1) physio-chemical characterisation or (2) microbiological biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing of specific devices, categories or groups of devices. Such expert laboratories are not yet designated as such under Regulation (EU) 2017/745. The functions of expert laboratories are listed in Article 106(10) [of Regulation (EU) 2017/745?], in particular point (c) thereof. It is essential to scope the needs of the medical device sector for such expert laboratories to be designated as well as to determine the availability of expert laboratories for providing such support.

The objective of this action is to ensure a smooth operationalisation of the EURLs that will be designated in Q4 2023 and to scope the needs in terms of services to be provided by expert laboratories and their availability.

The activities it aims to fund are:

- a) support for the EURL network during the transition period to become operational;
- b) preparatory activities for future EURL calls and designations;
- c) scoping study for the need and availability of expert laboratories to be designated in the field of medical devices.

This action will support the functioning of the EU Reference Laboratory networks that are set up in accordance with Article 100(5) of Regulation (EU) 2017/746 and assess the need to designate expert laboratories in accordance with Article 106(7) under Regulation (EU) 2017/745.

This action will contribute to the establishment of a uniform and rigorous regulatory environment and contribute to ensuring the availability of diagnostics and medical devices in the Union. Furthermore, this action will foster innovation in the field of medical devices and in vitro diagnostics through the availability of services to be provided by EURLs and expert laboratories, most notably through testing and scientific advice. This action will contribute to a high level of safety and performance of high-risk in vitro diagnostic medical devices and medical devices in the Union.

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

Indicative type of contracts/supply: administrative arrangement with JRC.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA / DG SANTE

D. ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT

In 2024, the Commission intends to undertake actions through indirect management mode, whereby the Commission delegates budget implementation tasks to third entities to achieve a set of Union objectives relying on their rules, systems, and procedures. Indirect management is the appropriate management mode for entrusting Union funds to international organisations that have undergone an ex-ante assessment of their rules, systems, and procedures - the so-called 'pillar assessment' - in accordance with Article 154(4) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (the 'Financial Regulation').

Further actions may be implemented in this work programme covering activities in the field of public health by implementing the EU4Health Programme's general objectives (Article 3, points (a) to (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) to (j), of Regulation (EU) 2021/522.

ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

CP-CA-24-92 Supporting the development of antibiotics to strengthen global preparedness and response (HERA)

POLICY CONTEXT

Antimicrobial resistance (AMR) is a major threat to health, which was associated to more than 35 000 deaths annually in the Union¹⁵¹ and against which efficient medical countermeasures, including antimicrobials, are lacking. HERA has thus included AMR in its preliminary list of priority threats and commissioned in 2022 a study on "bringing more AMR medical countermeasures on the market" as well as a study on "stockpiling antimicrobials and Active Pharmaceutical Ingredients".

These two studies provided evidence, including a mapping and prioritisation of medical countermeasures required to tackle AMR, both existing and in development, as well as an assessment of various policy options to promote the development, availability and access to AMR medical countermeasures. As regards the role of HERA towards push funding, the study on "bringing AMR MCM to market"¹⁵² provided notably that HERA "should ensure international alignment and avoid duplication of efforts" and that "there are currently a number of existing and established mechanisms of push support that would benefit from additional EU investment", mentioning for example the Global Antibiotic Research & Development Partnership ('GARDP'). Further, in their 2022 Meeting statement and Communiqué, both G7 and G20 Health Ministers encouraged efforts to close GARDP's funding gap to facilitate the "5 by 25" Initiative to deliver five new treatments by 2025.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, the WHO (in collaboration with GARDP) is the eligible legal entity to implement this action. The WHO has a crucial leadership in the global antibiotic availability and access, and it is the most appropriate entity with the required expertise and capacity for implementing the action.

¹⁵¹ Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016 – 2020 ([ECDC](#)).

¹⁵² CP-p-22-02.02 Study on tackling AMR, [2022 EU4Health work programme](#).

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures, with a focus on AMR. It implements the EU4Health Programme’s general objective of improving the availability, accessibility, and affordability of crisis-relevant products (Article 3, point (c), of Regulation 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to support ongoing and effective global initiatives coordinated by the WHO that can bring an added value to health protection in the Union by significantly improving pandemic prevention, preparedness, and response in the area of AMR. In particular, this action aims to support the WHO in collaboration with GARDP in providing push funding for the pre-clinical and clinical development of new, and in ensuring sustainable access to these treatments while promoting responsible use and affordability.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

- a) an increased development of AMR medical countermeasures;
- b) innovation in AMR medical countermeasures development;
- c) increased availability of AMR medical countermeasures.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Estimated call publication | Budget |
|-----------------------------|-----------------------------------|------------------------------------|
| CP-CA-24-92 | Q1-Q2/2024 | EUR 20 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Indirect management | HERA | WHO |

ACTIONS WITH A COST BELOW EUR 20 000 000

CP-CO-24-91 Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the Invest EU Programme¹⁵³ (HERA)

POLICY CONTEXT

The best way to master future health crises is to anticipate and prepare before they materialise. The Communication “Drawing the early lessons of the COVID-19 pandemic”¹⁵⁴ pointed to the need to further invest money and efforts in pandemic preparedness and response, via a broader toolbox for crisis situations. HERA was set up to strengthen Europe’s ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures.

A key task of HERA is to promote research and innovation to develop effective, safe, and affordable medical countermeasures and critical medicines. There is a need to combine public and private efforts to incentivize breakthrough research and innovation in the health ecosystem, making it more resilient.

This action will be conducted in accordance with Article 10 of Regulation (EU) 2021/522.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

With this action, HERA will contribute to the Thematic Innovation - Research, Innovation and Digitalisation Window (RIDW) financial product (more specifically, in the policy area ‘1.1 Health innovation investment’) implemented by the European Investment Bank (EIB) under the Invest EU programme. The budgetary amount will be EUR 10 million from EU4Health.

The aim of the action is to support investments into R&D of medical countermeasures for pandemic preparedness, in particular into vaccines and other preventive interventions, therapeutics (including critical medicines), and diagnostics, as mentioned in the guaranteed agreement between the EIB and the Commission. The funds will be managed by DG ECFIN via cross sub-delegation. The implementing entity is the EIB. HERA will cooperate with EIB for the successful implementation of the action.

The aim of the action is to support investments, through venture loans, into innovative European companies developing interventions (i.e., diagnostics, therapeutics, vaccines) against priority cross-border health threats (i.e., pathogens with high pandemic potential, AMR, CBRN). Currently, a market failure in the development of such interventions exists in the form of a lack of private investment due to the high-risk nature of such investments (i.e., low probability of success, low expected revenue). This action will provide support in the form of an additional guarantee that will further reduce the risk for potential investors, thereby incentivising private

¹⁵³ This blending operation is referred to as “HERA INVEST”.

¹⁵⁴ Communication on the early lessons from the COVID-19 pandemic ([europa.eu](https://european-council.europa.eu/media/en/press-communications/2020/05/154_en.pdf)).

investment, and contributing to the R&D pipeline of medical countermeasures against serious cross-border health threats.

At present, there is no European private or public/private financing facility specialising in providing financial support to the development of a wide range of medical countermeasures dealing with AMR, CBRN and pathogens with pandemic potential. International organisations such as CEPI¹⁵⁵ or the novel WHO/World Bank financial intermediary fund focus or will focus either on the development of only one class of medical countermeasures, or do not sufficiently fund end-to-end (early research to market) development of medical countermeasures. Moreover, their focus is international. Their investments do not always guarantee the Union development and availability of medical countermeasures in times of crises and may not meet the objectives of European strategic autonomy and resilience. HERA has a unique opportunity to alleviate this market failure and provide European autonomy in the development of lifesaving medical countermeasures.

Thanks to this action a number of priority health threats and medical countermeasures based on HERA’s prioritisation activities will be funded. Therefore, in order to ensure a better understanding of the extent to which market failures of suboptimal investments in medical countermeasures can be mitigated, investments will focus on projects targeting the development of preventative, treatment or diagnostics medical countermeasures for a specific group of pathogens. In addition, the investment should be made into early to late-stage SME life sciences companies developing a platform (i.e., tackling also other targets that are commercially attractive). This will allow for higher chances of repayment and economic success of the initiative.

EXPECTED RESULTS

This action can effectively incentivise private investment by leveraging public funds. A top-up of EUR 100m (in the form of a financial instrument) will contribute to the Thematic Innovation financial product, allowing the EIB to increase their volume of venture loans into specific areas as described above and bringing in other investors. A broad investment portfolio further minimises risks, especially if investments are made into platform technologies. Using a top up of a thematic financial product provides for control and ownership via the Invest EU eligibility checklist procedure, as well as inclusion of third parties.

The action aims at attracting third party investors through co-investment, for example from Member States, international donors and private investors. The action promotes innovation and development of new medical countermeasures and will create positive spill overs for international partners.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|-----------------|-----------------------|----------------|
| CP-CO-24-91 | Q1-Q3/2024 | EUR 10 000 000 |

¹⁵⁵ [CEPI | New Vaccines For A Safer World.](#)

| Procedure type | Implemented by | Implementing Entity |
|-----------------------|--------------------------------------|----------------------------|
| Indirect management | Co-delegation type II to DG ECFIN | EIB |

CP-CA-24-93 Support for implementing the diagnostics component of the 100 days mission (HERA)

POLICY CONTEXT

The COVID-19 pandemic demonstrated that it took too long to develop and scale-up production of the required diagnostic solutions. What is more, diagnostics to support surveillance and patient care for both endemic, epidemic and pandemic-prone pathogens are almost completely lacking at present, especially at the community and primary healthcare level, where pandemics most often begin.

In response, the G7 proposed the “100 Days Mission to Respond to Future Pandemic Threats” in which, within 100 days of the declaration of a major public health event by the WHO accurate and authorized diagnostics are to be available, alongside an initial regimen of therapeutics and vaccines ready to be produced at scale for global deployment. This action is supported by the Global Fund and more specifically by one of its partners FIND.

Drawing on these lessons learned from the COVID-19 pandemic, the Commission proposed to set up HERA, which was established through a Commission Decision on 16 September 2021. It was set up to strengthen Europe’s ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures. HERA therefore plays a vital role in delivering the 100 Days Mission and specifically advances the diagnostics component of the mission with this action.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522 the Global Fund is the eligible entity to implement this action. The award of the action to the Global Fund is duly justified by its crucial leadership, its convening and coordination role in global health, and in strengthening multilateral cooperation and in steering the world’s preparation and response to public health emergencies. Therefore, the Global Fund is the sole body with the required expertise and capacity to implement this action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the policy priority to be better prepared to respond to cross-border health threats. It contributes to the achievement of 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 with a focus on pathogens with pandemic potential (Article 3, point (b), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action supports the development of the diagnostic component of the 100 Days Mission through support to Global Fund and its partners, such as FIND, the global alliance for diagnostics. Analogous to CEPI for vaccines, FIND serves a coordinating role between industry and other global partners, identifying the most promising diagnostic platforms, securing key reagents and biobanked samples needed for development, and establishing partnership agreements with industry and other stakeholders to achieve relevant milestones. FIND also addresses the necessary regulatory processes and manufacturing capacity for the products developed under development agreements, and partners with global procurement agencies (such as GAVI and the Global Fund) to support mechanisms for sustainable test demand and test procurement, as well with the WHO on the necessary technical guidance and policies. This action will specifically support the Global Fund to operationalize the program of work required to achieve the “100 Day Mission for Diagnostics”. On this, FIND will partner and closely collaborate with HERA’s European laboratory network DURABLE. Relevant activities will be embedded within the framework of DURABLE, benefitting from synergies and avoiding duplication.

The 100 Day Mission includes building and validating diagnostic libraries for prototype pathogens and families. Through this, one of the objectives is developing molecular assays for priority pathogens. The action will also support work on rapid diagnostic tests (‘RDTs’), enabling the development of pan-virus family and/or pathogen-specific RDTs. To guide these activities, a global landscaping of existing pandemic diagnostics and reagents will be carried out in complementarity with existing initiatives such as DURABLE and the study on diagnostic solutions launched by HERA.

Complementing the development of both molecular assays and RDTs, this action will also support access to biomaterial (i.e., target virus isolates as well as clinical samples) as this is essential for diagnostic test development and validation, particularly for viruses of some families that relatively rarely emerge, such as Marburg and Nipah viruses. This cannot be done without access to well-characterized, high-quality biological samples that have been collected, processed, and stored in the correct place and in the correct way.

EXPECTED RESULTS AND IMPACT

This action will contribute to make the 100 Days Mission for pandemic preparedness a reality, detecting pathogens with pandemic potential as early as possible. The action will allow for the right diagnostic tests already developed, verified or validated, and available for routine use in the right settings to enable rapid detection of pandemic-prone pathogens and swift response to outbreaks. This early warning and response can significantly change the epidemic dynamics in the early stages of a disease outbreak.

The developed RDTs could allow for rapid, targeted deployment of other medical countermeasures such as vaccines and antibodies. RDTs and point-of-care devices also allow diagnostic access to communities or populations underserved by the health system without easy access to clinical or laboratory infrastructure. Enable the general population to know their infection status can be crucial for infection control in an outbreak scenario. Reliable diagnostics could drastically reduce or even avoid the need for lockdowns and the high associated economic costs. Diagnostic solutions widely available immediately after the identification of an outbreak could instead allow for an outbreak control strategy relying on isolation and contact tracing.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---|
| CP-CA-24-93 | Q1/2024 | EUR 11 600 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | HERA | The Global Fund to Fight Aids, Tuberculosis and Malaria |

CP-CA-24-94.1/2 Support strategies, capacity and data for global wastewater and environmental surveillance (HERA)

POLICY CONTEXT

The World Health Organization (‘WHO’) is the United Nations (‘UN’) specialized agency for health that directs and coordinates the world’s response to global public health emergencies, promotes universal health coverage and healthier lives. The United Nations Environment Programme (‘UNEP’) is the leading global authority on the environment. UNEP helps countries transition to low-carbon and resource-efficient economies, strengthening environmental governance and law, safeguarding ecosystems, and providing evidence-based data to inform policy decisions.

During the COVID-19 pandemic wastewater surveillance¹⁵⁶ was demonstrated in a range of settings to provide an important additional line of data that can support early detection of outbreaks, cost effective targeting of diagnostics and also augment uptake of risk communications among other uses¹⁵⁷. Such wastewater and environmental¹⁵⁸ surveillance have also been successfully deployed for many years for polio and illicit drugs and has been more recently trialled for other targets such as typhoid, cholera and antimicrobial resistance. However, common challenges have been; establishing timely and effective links to a well-defined data use for public health decision making, sustaining surveillance activities between the acute phase of outbreaks, developing sampling and laboratory methods that serve more than one disease or risk of interest, and adapting method for use in settings with low levels of sewer coverage. Another challenge has been the lack of training opportunities for practitioners and stakeholders on the application and benefits of wastewater surveillance for public health and preservation of ecosystem services.

The experience of wastewater surveillance for COVID-19 has ignited widespread interest and research on application of wastewater and environment surveillance for a variety of other targets, particularly respiratory and vaccine preventable diseases, for potential application at scale within wider global disease surveillance and response strategies. However, as yet, many

¹⁵⁶ Refers to sampling and analysis of wastewater from sewer networks.

¹⁵⁷ [Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance.](#)

¹⁵⁸ Refers to sampling and analysis of contaminated water bodies such as open drains in located without sewers networks more common in LMICs.

remain in research and pilot phase and potential for efficiencies and sustainability though combining strategies for multiple pathogens has not been well explored.

In accordance with Articles 7(1) and 13(1) point (b), of Regulation (EU) 2021/522 the WHO and UNEP are the eligible entities to implement this action. The award of the action to the WHO and UNEP is duly justified since WHO and UNEP are well placed to provide leadership on effective strategies and associated capacity development and data sharing about wastewater and environmental surveillance of multiple pathogens to support public health preparedness and response as part of a wider preparedness and response strategy. The WHO in its capacity as a norms and standards setting organisation can provide strategic direction on preparedness and response for a wide range of public health challenges where such surveillance is demonstrated to add value alongside clinical surveillance. UNEP in its capacity of the secretariat of the Global Wastewater Initiative can provide leadership on knowledge exchange on wastewater surveillance especially in countries where wastewater surveillance programmes are in the demand and not rolled out yet. Therefore, the WHO and UNEP are the sole bodies with the required expertise and capacity to implement this action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the policy priority to be better prepared to respond to cross-border health threats. It contributes to the achievement of 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), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is three-fold:

- a) to define wastewater and environmental surveillance strategies to contribute to preparedness and response;
- b) to develop capacity building strategies especially for low resource settings and in strategic locations;
- c) to contribute to global transparency in the exchange of data and collaboration.

EXPECTED RESULTS AND IMPACT

The action is expected to a result in:

- a) a decisions support tool is guiding global investment in wastewater and environmental surveillance to targets and use cases where it will have most impact on public health preparedness and response;
- b) clear guidance for countries and development partners on minimum capacity need and investment requirements to establish and sustain a credible wastewater and environmental surveillance programme;
- c) wastewater monitoring on aircrafts and airports carried out in up to three African airports;
- d) harmonised data collection and exchange that enables global and regional data use and decision making.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic /sub-topic | Estimated launch date | Budget |
|---------------------|-----------------------|--------------------|
| CP-CA-24-94. 1 | Q1/2024 | WHO EUR 3 000 000 |
| CP-CA-24-94. 2 | | UNEP EUR 3 800 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | HERA | WHO and UNEP |

CP-CA-24-107 Supporting logistical operations for medical countermeasures in Africa (HERA)

POLICY CONTEXT

In the past years, the WHO Operations Support and Logistics ('OSL') has significantly contributed to the emergency response in 28 countries of the African Region by providing support in terms of supply chain and service delivery during critical situations such as disease outbreaks, civil unrest, and weather-related events. As an example, in 2022, in response to the Uganda Ebola outbreak, OSL deployed medical countermeasures within 72 hours from Nairobi to Uganda to prevent the spread of this health threat. In addition, in response to the Viral Haemorrhagic Fevers ('VHF') outbreak in Equatorial Guinea in 2023, OSL ensured transportation of samples for testing to a referral laboratory and the shipment of emergency medical supplies including PPEs, VHF testing and sequencing reagents, and biomedical equipment to Equatorial Guinea within 72 hours. In addition, OSL, in close collaboration with the Africa CDC, conducts tailored training programmes in the areas of supply chain and health logistics for first responders. These achievements underscore the critical importance of coordinated efforts and preparedness to address emergencies swiftly and efficiently, and the critical role that the WHO OSL can play to enhance response capabilities.

One of HERA's missions is to contribute to reinforcing the global health emergency preparedness and response architecture, which includes the support to global initiatives to ensure medical countermeasure response to countering the spread of a health threat and to protect the health of people from serious cross-border health threats particularly in the Union. Even if the OSL has been effective so far in containing many of the outbreaks of concern in Africa, there is a need to further strengthen its activities particularly in Eastern Africa, given the increasing number of outbreaks of pathogen with pandemic potential in the area. In accordance with Articles 7(1) and 13(1) point (b), of Regulation (EU) 2021/522, WHO is the eligible legal entity to implement this action. WHO has a crucial leadership in the global response to outbreaks, and it is the most appropriate entity with the required expertise and capacity for implementing the action. The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures, with a focus on pathogens with pandemic potential and other priority threats. It implements the EU4Health Programme’s general objective of improving the availability, accessibility and affordability of crisis-relevant products (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action supports OSL's ability to manage the supply chain effectively and respond rapidly, especially by procuring and transporting medical countermeasures promptly in case of a health emergency.

In order to do so, this action will support the expansion of the stockpiling of critical medical countermeasures in regional hubs, in particular in the Dakar Hub, allowing for significant cost savings and reduction of lead times for critical supplies during emergencies in West and Central Africa. In addition, in order to ensure timely response, the action will include training programmes in the areas of supply chain and health logistics for first responders in order to ensure that there is an adequate implementation and management, and such supplies and response times are reduce as much as possible.

EXPECTED RESULTS AND IMPACT

This action will contribute to strengthen preparedness and response to cross-border health threats internationally and in particular to improve response capacities in West and Central Africa with a direct impact on outbreak control. It is expected that the WHO OSL Dakar will reach communities affected by emergencies within 72 hours and contribute to improving pandemic preparedness and strengthening healthcare delivery.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic /sub-topic | Estimated launch date | Budget |
|-------------------------|------------------------------|---------------|
| CP-CA-24-107 | Q1/2024 | EUR 1 500 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | HERA | WHO |

DI-CA-24-77 Strengthen global health by promoting and developing digital solutions at international level

POLICY CONTEXT

The use of digital solutions in healthcare contributes to strengthening health and quality of care including improving prevention and monitoring, facilitating access to and continuity of care, and fostering innovation and research.

The Union is pioneering the digital arena in areas such as regulation of health data, digital certificates, data sharing, data protection and privacy. In those areas, there is still some room for improvement particularly in converging towards common rules, norms, standards, and interoperability.

The Union aims to leverage the potential of health data worldwide by promoting and developing the principles and technical foundations of the use and reuse of health data with initiatives such as the proposed European Health Data Space, and by fostering the use of new technologies to boost their potential to improve prevention, diagnosis, and treatments worldwide.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, the WHO is the eligible entity to implement this action. The award of the action to the WHO is duly justified by its crucial leadership, for example as due to its central role in the Global Digital Health Certification Network ('GDHCN'), a convening and coordination role in global health, and in strengthening multilateral cooperation in digital health and health data and in steering preparation and response to public health emergencies. Therefore, the WHO is the sole entity with the required expertise and capacity to implement this action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

The action supports the Union's global commitments and health initiatives and the policy priority to advance in digital transformation of healthcare and implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (f) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims at strengthening health information systems and boosting the use and reuse of health data by, for instance, maintaining and supporting the further development of international systems, such as the WHO and the GDHCN, or by promoting the principles and solutions included in the proposed Regulation on the European Health Data Space ('EHDS'). This action will also contribute to the objectives of the new EU Global Health Strategy to improve global health security and deliver better health for all in a changing world.

This action will support the WHO with the promotion, maintenance, development and implementation of tools (e.g., the GDHCN), common rules, standards, systems, and capacity building activities to strengthen health information systems, health data governance, data quality and interoperability in the participating countries.

EXPECTED RESULTS AND IMPACT

This action is expected to deliver digital health technologies at a global level that support better health and well-being of people, strengthen health systems, advance universal health coverage, and enable better preparedness for health threats, including pandemics. The action will contribute to shaping the digital health ecosystem globally (rules, norms, standards,

interoperability), using and further developing European examples and best practices such as the technologies and trust framework used in the EU Digital COVID Certificate Regulation (EU) 2021/953 and the planned European Health Data Space, and supporting international rules that are compatible with the Union framework while facilitating person-centred health data governance and protection.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Call topic/sub-topic | Estimated call publication | Budget |
|-----------------------------|-----------------------------------|------------------------------------|
| DI-CA-24-77 | Q1-Q2/2024 | EUR 4 000 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Indirect management | DG SANTE | WHO |

CP-CA-24-3 Early Warning and Response System, implementation of Regulation (EU) 2022/2371 for the period of 2024-2027

POLICY CONTEXT

The Early Warning and Response System (‘EWRS’) has witnessed an unprecedented exponential increase in its use during the COVID-19 pandemic thereby showing limitations of the current version of the system which will be reinforced.

It is therefore vital to consider exactly how EWRS can be reinforced to fulfil the legal basis of the new Health Union Regulation and increase effective coordination across the European health security landscape in preparedness, alerting, public health risk assessment, and most critically, crisis response to protect public health in Europe.

In accordance with Article 18 of Regulation (EU) 2022/2371 on serious cross-border threats to health, the EWRS shall enable the Commission, the ECDC, and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alert notifications, assessing public health risks and determining the measures that may be required to protect public health.

Pursuant to Article 8 of Regulation (EU) 2022/2370, ECDC shall support and assist the Commission by operating the EWRS in accordance with Article 18 of Regulation (EU) 2022/2371 and by ensuring, together with the Member States, the capacity to respond to health threats in a coordinated and timely manner. The operation of EWRS comprise analysing the content of messages received via the EWRS, providing risk assessment, advice, and ensuring that the EWRS is efficiently and effectively linked with other Union alert information systems (‘AIS’). Additionally, ECDC is responsible for ensuring the legality, security, and confidentiality of the processing operations of personal data carried out within the EWRS, in accordance with Articles 33 and 36 of Regulation (EU) 2018/1725 of the European Parliament and of the Council.

Furthermore, ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for digitalised contact tracing tools, building upon the contact tracing technologies developed by the Member States.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, ECDC is the eligible legal entity to implement this action. ECDC plays a crucial role in supporting the Union and Member States in response to public health emergencies due to biological agents, and therefore, is the sole entity with the required expertise and capacity to implement the action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the implementation of Regulation (EU) 2022/2371 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), of Regulation (EU) 2021/522) through the specific objectives in Article 4, points (b), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aim is to upgrade the EWRS system in line with Regulation (EU) 2022/2371/.

The use of EWRS, which is to cover all threats in line with Article 2 of Regulation (EU) 2022/2371, should be facilitated by diversifying the type of users, linking the national competent authorities for the reporting of all health threats to the EWRS and by integrating the EWRS with the existing other Union alert and information system (AIS) with public health relevance.

In addition, new functionalities and modules will be developed for the EWRS to support the public health risk assessments (Article 20 of Regulation (EU) 2022/2371), the Union and national preparedness and response plans (Articles 5 and 6), the reporting on preparedness and response planning (Article 7) and support to crisis management (Article 21).

The EWRS data security and data protection will be improved, by considering the recommendations of the data protection impact assessment ('DPIA') and security audit report carried out in 2022.

Also this action will build on the results of the EWRS future developments assessment contract, funded under the EU4Health work programme 2021, under the BEACON DIGIT/2020/OP/0005 FWC, which aim to perform the assessment and proof of concepts of the EWRS platform future developments, including the reinforcement of the EWRS platform governance, architecture, capabilities, data protection and data security procedures and EWRS users' support, including capacity building training package.

The action's objectives are to:

- a) further progress development of the EWRS towards an 'all threats' approach;
- b) strengthen preparedness and response planning;
- c) strengthen data security;
- d) support the Union's and national crisis management capacities;
- e) develop and implement new modules to further support inter-sectorial communication and collaboration on risk assessment and crisis management;
- f) develop and implement capacity-building actions on the use of the EWRS in Member States and Commission services;

- g) streamline the EWRS procedures, services, and reporting;
- h) develop of a new EWRS platform to ensure high resilience and tolerance.

Short description of the activities per objective,

a) further progress EWRS towards an ‘all threats’ approach

- i. implement a new architecture, making efficient use of new technological developments, information sources, and analytical methods;
- ii. establish an institutional and technical framework for cooperation and automatic information exchange with EWRS, based on identified alert-and information system stakeholders and users;
- iii. integrate other alert and information systems into the EWRS, by creating a mechanism of pulling alerts from other AIS to EWRS, establishing a connection to at least eleven AIS platforms, including EpiPulse;
- iv. establish procedures and tools for validating the other AIS notifications that fulfil the criteria of a serious cross-border threat to health;
- v. extend the user roles and profiles, ensuring the involvement of all threats stakeholders and diversifying the EWRS different functions, to create communities of users per type of threat.

b) strengthen preparedness and response planning

- i. implement support for communication and coordination of national preparedness capacities and crisis management reports, in compliance with Article 7, including support for sharing EU Classified Information (EUCI) sensitive data, if required;
- ii. organise consultative workshops with country representatives to guide the implementation of new modules for preparedness planning and reporting, including support for a streamlined approach with regard to the International Health Regulations (IHR), State Parties Self-Assessment and Annual report (SPAR);
- iii. support sharing ‘lessons learned’, in relation to both simulation exercises and real events, especially across regions and between countries affected differently by an emerging public health crisis.

c) strengthen data protection and security

- i. implement the recommendations of the data security audit and data protection impact assessment to further improve data protection and security at Union and national level;
- ii. implement measures to strengthen EWRS security, ensuring compliance with requirements for the storage, processing, and electronic exchange of EU Classified Information (EUCI) in EWRS with Union institutions and Member States/EEA countries.

d) support the Union’s and national crisis management capacities

- i. reinforce and develop the Union’s and national crisis management systems, addressing all hazard threats;
- ii. promote the interoperability, inter-sectorial and inter-regional collaboration in crisis response by developing capacity building and simulation exercises.

e) develop and implement new modules to further support inter-sectorial communication and collaboration.

- i. develop a risk Assessment module that can support definition and execution of procedures for requesting, initiating, collaborating, finalizing, and distributing inter-sectorial risk assessments;

- ii. establish agreed mechanisms of digital information sharing and cooperation, building on the new legal basis for the Commission to request and collaborate with identified agencies for ad-hoc risk assessments and monitoring;
 - iii. implement a risk communication module that enables a timely risk and crisis communication response and employs information sources and analytical methods that support national risk communication focal points, including a crisis communication knowledge base;
 - iv. take action or develop an emergency coordination module to support the Advisory Committee, stipulated in Article 24, of Regulation (EU) 2022/2371, to exchange of information and coordination of public health crisis.
- f) develop and implement capacity-building actions on the use of the EWRS in Member States and Commission services.**
- i. for all categories of public health threats, develop guidance and training programme on applying the criteria for serious cross-border threats to health when reporting to EWRS;
 - ii. based on the training needs assessment report, implement continuous professional training for current and new EWRS users, at Commission services and national level on early warning and response for all threats, inter-sectorial collaboration with other alert and information systems, risk communication, crisis management and digital public health on crisis response, data protection and data security compliance at national and regional levels, including online trainings, tutorials, and ‘train the trainers’ courses for the EWRS administrators and users.
- g) streamline the EWRS procedures and services**
- i. increase efficiency and coordination between stakeholders using the platform and managing the system at Union and national level;
 - ii. streamline and implement the procedures for administration and moderation, building on the finding and recommendation by the data protection assessment to comply with the requirements of Regulation (EU) 2016/679 on the protection of natural persons regarding the processing of personal data and on the free movement of such data;
 - iii. develop the user support services with streamlined working arrangements for common and distinct services between helpdesks;
 - iv. establish an open EWRS user forum to share best practices, submit suggestions and issues, to communicate with and involve users in shaping the further development of EWRS;
 - v. establish a EWRS evaluation and reporting framework.
- h) develop of a new EWRS platform to ensure high performance and efficient functioning of the IT tool**
- i. assess the need and requirements for the re-design of the EWRS platform;
 - ii. support the development of a new EWRS platform re-design to ensure high resilience and tolerance and the required diversification of infrastructure to ensure the different EWRS modules and functionalities.

EXPECTED RESULTS AND IMPACT

The expected results are:

- a) reinforcement of the existing EWRS for all hazards, including chemical, biological, radio nuclear threats to health (‘CBRN’) by linking it with the other Union alert and

information system and diversifying the EWRS users to achieve all hazards threat reporting;

- b) identification and implementation of the new required features for the EWRS architecture to ensure a better information management and the right information reach the right authorities to support the serious cross border health threats response;
- c) improvement of the use of selective exchange for the secure transmission of personal data required for cross border contact tracing and support of medical evacuation;
- d) development of the new modules and EWRS required features, mainly on preparedness planning and reporting, risk assessment, crisis management, including risk communication;
- e) establishment of a training programme adapted to the EWRS capacity building needs related to the use of the EWRS platform, adapted to the new EWRS functions and roles and user support service;
- f) simplification of the procedures and services to increase efficiency and coordination between stakeholders using the EWRS system and the ECDC's operation of that system;
- g) reinforcement of the EWRS data protection and data security of the EWRS system function;
- h) strengthening of the Union's and national crisis management system to face all serious cross-border threats to health;
- i) re-designing of the EWRS platform to ensure high resilience and tolerance, and diversified infrastructure.

This action contributes to the implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health and of Regulation (EU) 2022/2370 amending the European Centre for Prevention and Control (ECDC) mandate.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

The duration of the project is planned for 2024-2027, and it will take into account the financial report produced by the European Centre for Prevention and Control for the Commission's health security unit and to the Health Security Working group on Threat detection and EWRS, supported by detailed documentation in accordance with the rules of the contribution agreement.

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---------------|
| CP-CA-24-3 | Q1/2024 | EUR 1 500 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | ECDC |

CP-CA-24-9 Antimicrobial Resistance Interventions and Projections

POLICY CONTEXT

Antimicrobial resistance ('AMR') is the ability of microorganisms to resist antimicrobial treatments, especially antibiotics. It has a direct impact on human and animal health. It carries a heavy economic burden due to higher costs of treatments and reduced productivity caused by sickness. It is estimated that AMR is responsible for more than 35 000 deaths per year in the Union and globally up to 700 000. The social and economic burden of antimicrobial resistance is huge, because of, for example, prolonged treatments, and higher medical costs and increased mortality. AMR costs the Union EUR 1.5 billion per year in healthcare costs and productivity losses and up to USD 100 trillion to the world economy by 2050.

USD action on AMR is centred on the 2017 European One Health Action Plan against AMR. It is built on three pillars: (1) making the EU a best practice region; (2) boosting research, development and innovation; and (3) shaping the global agenda. It provides a comprehensive framework for cross-sectorial actions to reduce the emergence and spread of AMR. The Mission Letter of Commission President von der Leyen to Commissioner Kyriakides calls for full implementation of the action plan and advocate of a global agreement on the use and access to antimicrobials. Union policy initiatives on AMR were put forth in 2023 consisting of a package comprising a proposal for a Council recommendation on AMR and AMR provisions as part of the legislative proposals to revise the Union's pharmaceutical legislation. Those will be taken into account for the future work of the Organisation for Economic Co-operation and Development ('OECD') funded under this action, together with the results of other studies, carried out at Union level, notably a study (concluded in 2023) on barriers to effective implementation of policies and measures in Member States.

In this context, a range of different policy options and interventions are available to Member States to combat AMR and reduce its burden on public health and healthcare systems. In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the OECD is the eligible legal entity to implement this action. The OECD analysis on the economic burden of AMR is needed to help narrow-down cost and cost-savings in the efforts to tackle AMR under different policy scenarios. Therefore, the OECD is the sole entity with the required expertise and capacity to implement the action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the development and implementation of effective and cost-effective policies and measures against AMR in the Union, 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), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This activity will follow-up on the OECD's previous work on AMR (with the support of the EU Health Programme), which produced a model to assess the economic impact of AMR under a range of different policy scenarios. Outputs can be used by Member States to develop and implement cost-effective measures to address AMR. The work will further develop the economic model, generate up-to-date results, and include activities to support the use of the model by Member States and stakeholders.

The current model assesses the effectiveness and cost-effectiveness of policy options to promote rational use of antimicrobials and preserve their efficacy. It focuses on prevention policies to promote prudent use of antimicrobials and to promote infection prevention and control in healthcare settings. It also includes the ‘One-Health’ approach that entails the transmission dynamics from animals, animal products and the environment to humans. The model also assesses the potential return on investment associated with prevention measures, including vaccination and other health technologies as alternatives to antibiotics extended to include a range of indirect costs for the economy as a whole and costs to the health sector. It also produces detailed estimates of the economic impact of AMR, on the health system and on the wider economy including via loss of contributions to the labour market and other factors. The model covers all Member States.

Workshops, training, and technical support will be provided to help staff from Member States and other countries associated to the EU4Health Programme to use the economic model as an input to policy making. A web-based user-friendly version will also be produced.

EXPECTED RESULTS AND IMPACT

This work will deliver important analytical results and build on the AMR modelling framework established by OECD and previously supported by the EU. It will enable updated estimates to be made of the costs and impacts of AMR with different policy scenarios as well as allow for comparison with previous estimates to evaluate progress over time (or lack thereof). It will also provide tools, information, and technical support to help Member States use the results to inform policy decisions.

Outputs of the model will include projections of AMR prevalence rates, healthcare system and wider societal costs associated with AMR as well as estimates of the effectiveness and cost-effectiveness of selected AMR prevention and control policies in Member States. Beyond the Union’s needs, an additional benefit of having this analysis performed by the OECD, is that OECD member countries beyond those of the Union will also benefit from these results. The Union can thereby export principles such as the ‘One-Health’ approach (addressing AMR in humans and animals) to wider OECD countries.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---------------|
| CP-CA-24-9 | Q1-Q2/2024 | EUR 600 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | OECD |

CP-CA-24-4 Public health risk assessments

POLICY CONTEXT

Where an alert is notified pursuant to Article 19 of Regulation (EU) 2022/2371 on serious cross-border threats to health, the Commission shall, where necessary for the coordination of the response at Union level referred to in Article 21 of the Regulation or at the request of the HSC or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures.

In accordance with Article 20(1), points (a) to (f), of that Regulation the risk assessment shall be carried out by one or more of the following Union agencies or bodies: European Food Safety Authority ('EFSA'), European Chemicals Agency ('ECHA'), European Environment Agency ('EEA'), European Monitoring Centre for Drugs and Drug Addiction ('EMCDDA'), EUROPOL, European Medicines Agency ('EMA').

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, EFSA, ECHA, EEA, EMCDDA, EUROPOL, EMA are eligible legal entities to implement this action. They play a crucial role in strengthening cooperation among the Union and Member States actors in conducting risk assessment in response to public health emergencies, and therefore, are the sole entities with the required expertise and capacity to implement the action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This multiannual action supports the implementation Regulation (EU) 2022/2371 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), of (EU) Regulation 2021/522) through the specific objectives in Article 4, points (b), (i), (j) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action's objective is to be prepared where an alert is notified to allow the Commission to make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures.

EXPECTED RESULTS AND IMPACT

This action contributes to the implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---------------|
| CP-CA-24-4 | Q1-Q2/2024 | EUR 600 000 |
| Procedure type | Implemented by | Entity |

| | | |
|---------------------|----------|---|
| Indirect management | DG SANTE | EFSA, ECHA, EEA, EMCDDA, EUROPOL, EMA |
|---------------------|----------|---|

CP-CA-24-8 Sterile Insect Technique (SIT) approach as tool to suppress yellow fever mosquito (*Aedes aegypti*) on Cyprus and to build capacity for the use of this vector control technique in the Union

POLICY CONTEXT

Vector-borne diseases are on the rise due to climate change, including those transmitted by mosquitos. Regulation (EU) 2022/2371 specifically calls for collaboration under a one health umbrella considering health actions within the wider ecosystem to include environmental and animal health.

Regulation (EU) 2022/2371 and Regulation (EC) No 851/2004 as amended by Regulation (EU) 2022/2370 provide for strengthened actions for prevention, preparedness, and response against serious cross-border threats to health. Specifically, Article 13 of Regulation (EU) 2022/2371 provides for surveillance including surveillance for determinants of health.

Cyprus has notified of the recent establishment of a localised population of *Aedes aegypti* in Larnaca and of *Aedes albopictus* in Limassol. The detection of *Aedes aegypti* and the presence of *Aedes albopictus* would increase substantially the risk of outbreaks of dengue, Zika and chikungunya if both vectors would fully colonize Cyprus. The establishment of *Aedes aegypti* in Cyprus might also represent a risk for its subsequent establishment in other European countries and for the introduction in the Union of yellow fever disease.

The application of Sterile Insect Technique (‘SIT’) leads to females mostly laying sterile eggs, and population reduction. In case of a recently established invasive species, the population is likely to still be relatively small; therefore, SIT is likely to be particularly effective in such situations. Moreover, the *Aedes aegypti* identified by vector surveillance in Cyprus show resistance to insecticide making their use not a good alternative option to SIT.

The International Atomic Energy Agency (‘IAEA’) has been supporting Cyprus and other countries with SIT use for prevention and contingency plans preparation to respond to the detection of vectors of diseases. The STI requires a low dose radiation to sterilize male mosquitos that is why the agency has several years of expertise with this technique.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, the IAEA is the eligible entity to implement this action. The award of the action to IAEA is duly justified by its crucial leadership, a convening and coordination role in strengthening multilateral cooperation and in steering preparation and response to public health emergencies. Therefore, the IAEA is the sole entity with the required expertise and capacity to implement this action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the implementation of Regulation (EU) 2022/2371 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), of Regulation (EU) 2021/522) through the specific objectives in Article 4, points (b), (i), (j), and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The project aims to contribute to the IAEA work in cooperation with the Ministry of Health of Cyprus to train, supervise laboratory technicians for the production of *Aedes aegypti* mosquitos to be used in Cyprus to suppress *Aedes aegypti*.

The project shall also strengthen the capacity of neighbouring and candidate countries and potential candidates to familiarise with this technique via capacity building activities (training and workshops).

A final report highlighting the results in terms of mosquito suppression and needs for mosquito eradication shall be produced, also discussing ethical issues.

The manual should guide countries that would consider the establishment of in country facilities which would allow production of higher quantity of sterile mosquitos for their eradication projects and potentially for supporting other Member States eradicating harmful vectors.

The manual should explain and guide on how to adapt the production to target elimination of other mosquito species also diseases carriers (such as *albopictus*) and of insects harmful for plants and animals.

The manual should address safety aspects related to the SIT including related to transport of mosquitos to other Member States.

EXPECTED RESULTS AND IMPACT

Documentation of the progresses with the suppression of *Aedes aegypti* from Larnaca, Cyprus.

Availability of laboratory technicians in Cyprus and other Member States and candidate countries and potential candidates familiar with the SIT.

Availability of a manual to guide the establishment of SIT producing facilities, including guidance for safety measures and shipment of sterile mosquitos to other countries.

Under the current trend of climate change related temperature raise, more countries might face similar problems in the coming years, so if proved successful the experience of Cyprus with SIT could provide support to other Member States.

Aedes albopictus, against which SIT can also be used, is already established in several Mediterranean countries that have already reported locally acquired dengue cases.

Lastly, the breeding facilities and equipment should be appropriate or adaptable for the production of sterile males of different mosquito species that are vectors of other diseases and potentially could be used for pests affecting plants and livestock.

This action contributes to the implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health threats, on detection, prevention, and response to One Health approach.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---------------|
| CP-CA-24-8 | Q1/2024 | EUR 500 000 |
| Procedure type | Implemented by | Entity |

| | | |
|---------------------|----------|---|
| Indirect management | DG SANTE | International Atomic Energy Agency (IAEA) |
|---------------------|----------|---|

CP-CA-24-6 Antimicrobial resistance and healthcare associated infections

POLICY CONTEXT

Antimicrobial resistance (‘AMR’) is an increasing global health threat and responsible for an estimated at least 35 000 deaths in the EU/EEA. The global social and economic burden of AMR is huge, because of, for example, prolonged treatments, higher medical costs, and increased mortality. The World Bank estimates possible cumulative losses of 100 trillion USD to the world economy by 2050. Evidence shows that financial savings can be made from a closer cooperation of human, animal and plant health and the environmental sectors and may contribute to prevent future outbreaks. A large part of reported AMR cases is due to healthcare-associated infections, underlying the need to address hospitals and long-term care facilities.

In June 2017, the Commission adopted the European 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 European One Health Action Plan against AMR, 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 WHO Regional Office for Europe is a major normative player in the European Region. In October 2023, the WHO Regional Office for Europe will be adopting the new Roadmap on antimicrobial resistance for the WHO European Region 2023–2030. This action will support the WHO Regional Office for Europe with the implementation of the new regional Roadmap among Member States and EU4Health associated countries, thus also contributing to the overall strengthening of AMR policies and measures in the EU.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522 the WHO (in particular the WHO Regional Office for Europe) is the eligible entity to implement this action. The award of the action to the WHO Regional Office for Europe is duly justified by its crucial leadership, a convening and coordination role in global/regional health, and in strengthening multilateral cooperation and in steering preparation and response to public health emergencies. Therefore, the WHO Regional Office for Europe is the sole entity with the required expertise and capacity to implement this action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action implements the EU4Health Programme’s general objective of protecting people in the Union from serious cross-border threats to health and strengthening health systems (Article 3, points (b) and (d), of Regulation (EU) 2021/522) through the specific objectives in Article 4, points (a), (b), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

To contribute to the work of the WHO Regional Office for Europe in the field of AMR and healthcare-associated infections.

EXPECTED RESULTS AND IMPACT

This action contributes to health in all policies, the Union’s One Health approach, and the European One Health Action Plan against AMR.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|---------------------|-----------------------|---------------|
| CP-CA-24-6 | Q1-Q2/2024 | EUR 1 000 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | WHO |

DP-CA-24-95. 1/2 Supporting Long COVID patients: insights and action

POLICY CONTEXT

The negative impact that Long COVID affected both health systems, and economies. While a lot of progress has been made in understanding Long COVID, we still need the science to give more answers about its causes and the best ways to treat the condition.

To address this challenge, international collaboration is needed in the Commission and Member States. To promote international collaboration, the Commission set up a high-level informal Network of Expertise on Long COVID (‘NELC’). It brings national centres of expertise on the management of Long COVID into contact with each other, to exchange countries’ experiences and best practices on the diagnosis, treatment, and management of Long COVID patients, and collect information regarding the situation on Long COVID in the different countries. The members of the network could prepare clinical guidelines, where possible, discuss case definitions, and/ or suggest applied research priorities. The Commission might organise exchanges of experts between countries’ centres of expertise and support capacity building to work on finding shared solutions. Given that for several topics, parallel efforts take place in Member States, we propose that the network could decide to form thematic working groups to promote more coordinated efforts and a targeted exchange of information. Additionally, Union agencies and other relevant actors or projects working on Long COVID might be invited to join the network. The additional members of the network (such as the WHO Europe) could provide latest evidence, inform the network about their activities, use the network for gathering information or inviting its members to participate in specific actions or projects, or join thematic working groups.

Next to the closed network of expertise, we propose to create a stakeholder network on the EU Health Policy Platform that could be joined by organisations representing patients and health professionals.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the OECD and the WHO are the eligible legal entities to implement this action. The OECD and the WHO have a crucial leadership, convening and coordination role in global health, in strengthening the world’s preparation and response to public health emergencies. Therefore,

the OECD and the WHO are the sole entities with the required expertise and capacity to implement the action.

This action implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), (e), (f), (g), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

Key objectives and activities include at least:

- a) establishing and monitoring the actual scale of the Long COVID syndrome across the EU. That shall include, but not be limited to developing common definition on Long COVID, based on recent scientific evidence; establishment of surveillance system on national and Union levels; assessment of social and economic consequences of the syndrome;
- b) supporting experts on national level in gaining the most up-to-date knowledge on Long COVID and ensuring, that their works targets real needs of the citizens. That shall include organisation of variety of webinars and meeting for members on NELC only, NELC and wider audience, and meetings, webinars, and other formats, that will allow for a mutual flow of feedback between NELC and stakeholders' network;
- c) activities that will help identify current needs from various areas and different angles, to assure, that broad range of scientific, and social needs are covered. Within it should be included the identification of the most urgent research gaps and needs, organisation of citizens panels, workshops and discussions for patients, healthcare staff and relevant stakeholders to create a space to exchange their experience, needs and Long COVID-related health policy;
- d) actions that will increase level of competences and knowledge among policymakers, healthcare staff, patients and any other relevant actors, who are involved in managing the consequences of Long COVID. This area should include among others: organisation of trainings for healthcare staff and healthcare system officials, exchange of experts, exchange of best practices and intelligence of diagnosis and treatment, development of common guidelines of Long COVID management, exchange of experience on the establishment of rehabilitation programmes, recommendation of for adapting the equipment of hospitals and clinics treating Long COVID patients;
- e) Organisation of a conference with wide audience, including policy makers, experts, stakeholders, and patients that will allow to present current achievements and progress, but also identify further needs and future actions and challenges, both at the Union level and globally.

EXPECTED RESULTS AND IMPACT

Abovementioned actions will allow to:

- a) improve the coherence of actions of Member States in the following areas: definition, surveillance including better surveillance at Union level, better comparability of health data at Union level;
- b) increase awareness and knowledge among experts, policymakers, and healthcare workers;
- c) improve to undertake actions which will directly address patients, and healthcare workers needs;

- d) ensure the improvement of the quality of patients care, by a coordination of care from various health areas, and a development of multifaceted and holistic approach in Long COVID management;
- e) strengthen the collaboration between the Union, third countries and relevant international organisations such as the WHO and the OECD.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|--------------------------------|------------------------------|---------------------------------------|
| DP-CA-24-95.1 DP-CA-24-95.2 | Q2/2024 | OECD EUR 1 500 000 WHO EUR 500 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | OECD and WHO |

DP/CR-CA-24-26 Promoting a comprehensive, prevention-oriented approach to children’s health

POLICY CONTEXT

In 2022, the Commission presented the ‘Healthier together’ – EU Non-Communicable Diseases Initiative (EU NCD Initiative) to support Member States in identifying and implementing effective policies and actions to reduce the burden of major non-communicable diseases (NCDs) and improve citizens’ health.

The Initiative covers the period 2022-2027 and includes five strands: 1) a horizontal strand on shared health determinants, focusing on population-level health promotion and disease prevention of NCDs (complementing the actions of Europe’s Beating Cancer Plan); 2) diabetes; 3) cardiovascular diseases; 4) chronic respiratory diseases; and 5) mental health and neurological disorders.

Financial support under the EU4Health work programmes 2022 and 2023 has been provided to support the implementation of actions identified by Member States under the above-mentioned strands.

After the first wave of support to Member States in the context of the EU NCD Initiative, it is important to adjust and improve its functioning by:

- a) further refining the identification of best practices, innovative policies, and cost-effective approaches that can deliver population impact;
- b) suggesting clusters of Member States to team up and cooperate closely on implementation of actions addressing common challenges;
- c) and addressing specific areas to better support vulnerable populations and/or uncovered areas.

This especially applies to children as a particularly important and vulnerable population group. In Europe's Beating Cancer Plan, the Commission announced that it would put forward actions to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2040, compared to around 25% today. The Commission intends to launch a revision of the 2009 Council Recommendation on smoke-free environments by the end of 2023. Since 2009 there have been technological advancements and an increase in market shares of emerging tobacco products (such as e-cigarettes and heated tobacco products). In addition, the 2009 Recommendation includes indoor and enclosed spaces in its scope but other public spaces such as certain outdoor spaces are only covered on a case-by-case basis. With the revision, the key objective is to protect people in the Union from exposure to second-hand smoke and aerosols. It will address risks from emerging products or from exposure to second-hand smoke and aerosols in certain outdoor spaces.

Commission President von der Leyen, in her State of the Union address in September 2022, announced a new initiative on mental health. Prior to this, at the Conference on the Future of Europe in May, European citizens had highlighted mental health as a major concern. Both the European Parliament and the Council called for action in this area. The Commission presented a Communication on a comprehensive approach to mental health on 7 June 2023, which was included in the Commission's work programme for 2023 under the priority 'promoting our European way of life'. The Communication recognises that the promotion of good mental health, prevention of mental health problems and early interventions are more effective and cost-effective than treatment. It also recognises that children and young people are affected by interconnected health determinants, such as nutrition, physical activity and tobacco, and environmental, social and commercial determinants with a potential impact on their mental health.

The mental health of children, adolescents, and young people has been emphasised as an important topic in a variety of sectoral dialogues with citizens, as well as in the European Year of Youth. The 2022 edition of the OECD report 'Health at a Glance: Europe' launched in December 2022 addresses the impact of COVID-19 on young people's mental health.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, UNICEF is the eligible legal entity to implement this action. UNICEF has a crucial leadership, convening and coordination role in global health, in strengthening multilateral cooperation and in steering the world's preparation and response to public health emergencies. Therefore, UNICEF is the sole entity with the required expertise and capacity to implement the action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the implementation of Europe's Beating Cancer Plan and the Tobacco-Free Generation, the Union/Global policy on Mental health and implements the EU4Health Programme's general objective to improve and foster health in the Union and to strengthen health systems by improving their resilience and resource efficiency (Article 3, points (a) and (d), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), (g), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to promote good physical and mental health and prevent mental health problems in children, adolescents, and young people through impactful actions across settings.

It will also support Member States in implementing the flagship actions and other initiatives of the Commission Communication on a comprehensive approach to mental health with a specific focus on children.

This action can also support increasing vaccination coverage rates among children, with a focus on catch-up vaccination after delays due to the COVID-19 pandemic.

The activities could include:

- a) developing and carrying out a survey among Member States to assess their capacities and needs on children's health promotion, disease prevention policies and programmes, including on promoting good mental health;
- b) preparing a report mapping the status and needs of children in the Union, in the context of health promotion, disease prevention and management of health problems, including mental health;
- c) designing a capacity-building programme for Member States on children's health and well-being, including mental health;
- d) developing of guidance for promotion of health and well-being, and prevention of health problems across settings for children, including mental health;
- e) developing of a methodology and/or tools to support early detection and intervention for children and adolescents to address potential health challenges, including mental health problems;
- f) designing and rolling out of an awareness campaign on positive physical and mental health and well-being, and on breaking stigma associated with mental health;
- g) developing integrated and coherent policy approaches to children's key health challenges, such as those that the digital world poses to children (e.g., misinformation, cyberbullying, body shaming, aggressive marketing, including to promote emerging tobacco products, undue access to and sharing of inappropriate content);
- h) creating and rolling out of a model for a multisectoral network for children's physical and mental health across policies at national level for sharing information, to develop interventions and policies, including on the 'de-normalisation' of the use of emerging tobacco products;
- i) developing of a training package for educational settings on children's health (physical and mental);
- j) identifying and implementing impactful best and promising practices for interventions for children, adolescents, young people and families in different settings;
- k) Developing communication tools to raise awareness of the importance of catch-up vaccination among children after delays due to the COVID-19 pandemic.

Activities will be carried out in coordination, as needed, with relevant stakeholders and international organisations, such as WHO, OECD and IFRC, and in synergy with existing networks, in order to avoid duplication of activities funded under the EU4Health Programme and in particular action DP-g-22-07.05¹⁵⁹ under the 2022 EU4Health work programme.

EXPECTED RESULTS AND IMPACT

The expected results of this action include improved health promotion and prevention of health problems, fostering Member States' capacities in addressing health needs of children, and improving the knowledge of children's public health needs and how to address them effectively, including as regards mental health.

¹⁵⁹ DP-g-22-07.05 Mental health and psychosocial support for displaced people coming from Ukraine. [2022 EU4Health work programme](#).

The needs of vulnerable groups of children, such as displaced children from Ukraine, refugees/migrants, and Roma children, will be a specific focus.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|---------------------|-----------------------|---------------|
| DP/CR-CA-24-26 | Q1-Q2/2024 | EUR 2 000 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | UNICEF |

DP/CR-CA-24-30 Health promotion and disease prevention: reducing the burden of NCDs, including cancers caused by infections and vaccine-preventable cancers, and promoting mental health

POLICY CONTEXT

The 2022 edition of the OECD report ‘Health at a Glance: Europe’ reported that the COVID-19 pandemic has led to a reduction of more than one year in life expectancy in the Union in 2021 compared with the pre-pandemic level.

One of the lessons from the pandemic is that maximising people’s health and minimising their exposure to risk factors before a crisis is critical. The prevention of behavioural and environmental risk factors can go a long way to improving people’s health and reducing the prevalence of chronic diseases and deaths.

The report noted that the pandemic has had a major impact on the mental and physical health of young people. In several European countries such as Belgium, Estonia, France, Sweden and Norway, the share of young people reporting symptoms of depression more than doubled during the pandemic, reaching prevalence levels at least twice as high as in older age groups. In addition, many children and young people also spent considerably less time engaging in physical activity and had worsening nutrition habits, with indications of a rise in childhood overweight and obesity in some countries. The report concluded that the growing demand for mental health support, combined with disruptions in care delivery during the pandemic, challenged already-stretched mental health services. About 50% of young Europeans reported unmet needs for mental healthcare in spring 2021 and again in spring 2022. According to the OECD, many countries have implemented some measures to protect and care for young people’s mental health, yet the magnitude of the impact warrants further action to ensure the pandemic does not leave permanent scars on this generation.

The pandemic also disrupted the provision of primary care, and cancer screening and treatment. Screening rates for breast and cervical cancer fell by 6% on average in the Member States in 2022¹⁶⁰. This has raised serious concerns as postponed diagnoses inevitably result in cancer being diagnosed at a later stage, making treatment more complex and reducing the probability of survival. Most Member States still have a way to go to reach the ambitious goal set out in

¹⁶⁰ Health at a Glance: Europe 2022 (OECD).

the Europe's Beating Cancer Plan of having 90% of the Union population who qualify for breast, cervical and colorectal cancer screenings offered screening by 2025¹⁶¹. The continuity of routine vaccination programmes was also challenged by the health crisis.

Health spending remained focused on curative care, with only 3% of total health spending going toward prevention on average in the Member States.

Preventable risk factors to health, such as smoking, alcohol consumption, illicit drug use, unhealthy nutrition, lack of physical activity, overweight and environmental risk factors should be addressed. Less than one in eight European adults reported consuming the recommended five portions of fruit and vegetables a day in 2019, and less than one in three performed at least 150 minutes of physical activity per week. As a result, more than one in two European adults were overweight or obese in 2019. Air pollution also has serious public health consequences in Member States, such as increased premature deaths due to heart disease and stroke, and lung diseases and cancer.

High alcohol consumption is associated with an increased risk of heart diseases, stroke, liver cirrhosis, certain cancers, but even low alcohol consumption increases the long-term risk of developing such diseases. Alcohol use was responsible for about 295 000 deaths across Member States in 2019 (IHME, 2021). Europe's Beating Cancer Plan aims to support Member States in reducing harmful alcohol consumption in line with the targets of the UN Sustainable Development Goals and to reduce young people's exposure to alcohol marketing.

Respiratory diseases are the third cause of death in Member States, leading to about 364 000 deaths in 2019 or 8% of all deaths. Chronic obstructive pulmonary disease ('COPD') is the most common cause of mortality among respiratory diseases, followed by pneumonia. Tobacco smoking is also the most important risk factor for COPD. One of the tobacco related objectives of Europe's Beating Cancer Plan is to create a Tobacco-Free Generation where less than 5% of the population uses tobacco by 2040, compared to around 25% today.

A considerable number of cancers are caused by infections, including *Helicobacter pylori*, Human Papillomavirus, Hepatitis B and C. One of the flagship initiatives of Europe's Beating Cancer Plan is to support the Member States' efforts to extend routine vaccination against HPV of girls and boys in order to eliminate cervical cancer and other cancers caused by HPV, in particular anal and head-and-neck cancers. Furthermore, the Cancer Plan promises to help ensure access to vaccination against HBV and to treatments of Hepatitis C infections, which are associated with liver cancer.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the Organisation for Economic Co-operation and Development ('OECD') is the eligible legal entity to implement this action. The OECD has a crucial leadership and has the required experience in modelling health interventions and in identifying effective and evidence-based interventions at a national level, including support for countries on implementing them. Therefore, the OECD is the sole entity with the required expertise and capacity to implement the action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the reduction of the burden of NCDs, including cancers caused by infections and vaccine-preventable cancers, and the improvement of mental health in the Union and implements the EU4Health Programme's general objective to improve and foster health in the Union and to strengthen health systems by improving their resilience and resource

¹⁶¹ [Europe's Beating Cancer Plan](#).

efficiency (Article 3, points (a) and (d), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), (g), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to reduce the burden of NCDs, including cancers caused by infections and vaccine-preventable cancers, and to supporting mental health in the EU, both at individual and population level, and to support Member States in their efforts to meet the health-related Sustainable Development Goals, as well as the NCDs targets of the WHO¹⁶².

The activities will include:

- a) identification of cost-effective and evidence-based practices and approaches to support the reduction of the burden of cancers caused by infections, including vaccine-preventable cancers, and NCDs, including by promoting children's healthy development from a comprehensive perspective;
- b) in this context, support to Member States and/or other Countries to pilot and roll-out the practices and approaches identified, with tailor-made approaches if needed;
- c) development of European guidance and a toolkit for policy and decision makers, health and social professionals, and educators on approaches, promising and best practices to address health determinants, also addressing children's health stressors;
- d) modelling the impact of such approaches and practices and estimate the effect on health, financial and other relevant policy areas, including the impact on health budgets and the GDP;
- e) in collaboration with relevant stakeholders and international organisations, such as UNICEF, and in synergy with existing networks, such as European Burden of Disease Network, identification of countries with similar public health needs, including on vaccination, and cluster them in view of targeted efforts in the field;
- f) development of comprehensive solutions to support the efforts of the Member States in achieving the health-related SDGs and NCD targets of the WHO and other relevant international targets, and identification and cooperation with key stakeholders in the implementation of the actions;
- g) knowledge generation and analysis, including with anticipatory and modelling capabilities;
- h) support to Member States, in collaboration with the Commission on technical work and assessments related to efforts to reduce NCD burden, including promotion of mental health.

EXPECTED RESULTS AND IMPACT

The expected results of this contribution agreement are:

- a) European guidance and toolkit, including identification of best practices and evidence-based recommendations for promising high-impact policies; available in official Union languages and possible other languages;
- b) a factsheet for each Member State, identifying the gaps, obstacles, enablers and opportunities for each Member State in health promotion and disease prevention, including opportunities to cluster and team up with other countries;
- c) tailor-made support for Member States in developing and rolling out national plans on health promotion and disease prevention, management of NCDs as well as of cancers caused by infections and vaccine-preventable cancers, with a specific focus on children.

¹⁶² Set of 9 voluntary global NCD targets for 2025 ([WHO](#)).

The short and mid-term impacts are expected to contribute to improving health promotion, disease prevention and management of communicable diseases and NCDs, including cancer and mental health, across the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---------------|
| DP/CR -CA-24-30 | Q2/2024 | EUR 3 000 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | OECD |

HS-CA-24-46 Nurses at the heart of more resilient health systems and safe healthcare

POLICY CONTEXT

The core objective of the European Health Union, which is to protect the health of citizens, cannot be achieved without sufficient and well-qualified health workforce. Yet the shortage of nurses is a burning issue in more than half Member States and a trend of nurses quitting the profession due to stress and unattractive working conditions is accelerating after the COVID-19 pandemic. Furthermore, the data on age structure of nurses is alarming and the pipeline of new nurses in many Member States is insufficient to meet current and future demand for healthcare. Ageing of the population itself will result in considerable increase of demand for healthcare, especially for services which are provided by nurses. This is posing a risk to the safety of patients.

Some Member States historically have relied on foreign health workers. The increase in hiring nurses from non-EU countries may be an attractive and often cost-efficient approach to address the challenge of shortages. However, given the shortages of resources in health systems of non-EU countries, this may become a less viable option in the future.

Although the problem of structural shortages of nurses is widely recognised, progress towards addressing challenges remains insufficient. The action at Union level is necessary to attract more policy attention to the problem and mobilise efforts and collaboration to boost policies to create a more solid Union pool of nurses in Member States. In spirit of the Global Health Strategy and its guiding principle 6 calling for addressing workforce imbalances, this action will complement bilateral projects with partner countries, helping to reduce the dependence of Member States on nurses from non-EU countries.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, the WHO is the eligible entity to implement this action. The award of the action to the WHO is duly justified by its crucial leadership, its convening and coordination role in global health, and in strengthening multilateral cooperation and in steering the world’s preparation and response to public health emergencies. Therefore, the WHO is the sole entity with the required expertise and capacity to implement this action.

The starting date of the action may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

The action supports the Union's EU's global commitments and health initiatives, and it implements the EU4Health Programme's general objective to strengthen the health system (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (g), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The scope of this action is to work on solutions to increase the supply of nurses, building on the expertise of European nurses associations and their partner organisations in all the Member States, and reaching the policy level to ensure a quicker take up of necessary measures to alleviate the crisis of the nurse workforce.

This action will pursue two objectives:

- a) building up the pool of European nurses to counteract structural shortages of nurses in the Union and their negative impact on other regions of the world (traditional origin countries of migrant nurses);
- b) drive more policy focus and mobilise efforts to address the critical situation of nurses in order to improve resilience of health systems and safety of care, which are the central objectives of the European Health Union.

The action will cover Member States and it will focus on measures to attract more students and people in mid-careers to nursing professions, and on measures to retain nurses.

The activities will be the following ones:

- a) measures to attract more students and people in mid-careers to nursing professions:
 - i. mentoring programmes to attract new generation of young nurses;
 - ii. training/mentoring programmes for people in professional reorientation /mid-careers to attract them to nursing professions;
 - iii. collection of evidence on young people's interest in pursuing career in nursing and policy feedback.
- b) measures to retain nurses:
 - i. nurse workforce impact assessments to understand the problems behind the structural shortages, to take stock of lessons from the COVID-19 pandemic and reverse the trend of nurses quitting the profession;
 - ii. twinning strategies to improve workload management and ensure safe staffing levels;
 - iii. training for nursing associations and for managers on effective approaches to safe staffing levels and workload management;
 - iv. good practices in multi-disciplinary co-operation showing the strong role of nurses and value of their work and roles;
 - v. twinning strategies for more attractive career options;
 - vi. leadership course for nurses in service and systems improvements;
 - vii. good practices on the role of nurses in improving safety of care through research on better health outcomes achieved through validation of results of care and advocating for policies for societies and their health.

EXPECTED RESULTS AND IMPACTS

The expected results of the ‘Measures to attract more students and people in mid-careers to nursing professions’ are the following:

- a) mentoring/training programmes to attract more young people to nursing professions implemented in at least half of Member States (prioritising those with the most severe nurse shortages);
- b) mentoring/training programmes to attract more people in mid-careers to nursing professions implemented in at least half of Member States (prioritising those with the most severe nurse shortages);
- c) the delivery of a report with an analysis of evidence on young people’s interest in pursuing a nursing career and a policy dialogue at Union level.

The expected impact is:

- a) attracting more people to the nursing professions as attractive career and professional reorientation options.
- b) driving more policy focus and mobilising Member States’ efforts to take more decisive measures to address nurse shortages.

The expected results on the ‘Measures to retain nurses’ are the following:

- a) nurse workforce impact assessments in at least half of Member States carried out in hospitals, primary care and community care centres;
- b) twinning strategies to ensure safe staffing levels in at least half of Member States;
- c) training for nursing associations and for managers on effective approaches to safe staffing levels and workload management in at least half of Member States;
- d) good practices programme on the role of nurses in the multi-disciplinary co-operation and in providing safer care;
- e) strategies for more attractive career options for nurses in at least half of Member States;
- f) leadership course for nurses in service and systems improvements.

The expected impact is to:

- a) increase attractiveness of nursing careers;
- b) improve working conditions of nurses;
- c) improve safety of care;
- d) improve resilience of health systems;
- e) involve nurses in policy solutions.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|------------------------|------------------------------|---------------|
| CP-CA-24-46 | Q1/2024 | EUR 1 300 000 |
| Procedure type | Implemented by | Entity |
| Indirect management | DG SANTE | WHO |

HS- CA-24-58 Support for Substances of Human Origin

POLICY CONTEXT

While the Union legislation defines safety and quality rules, the Council of Europe -European Directorate for the Quality of Medicines and HealthCare ('EDQM') works with professional experts and authorities to develop and disseminate technical guidelines to ensure a standardised effective approach to the application of the rules. EDQM's guidelines are therefore expected to become a formal point of reference in the proposed Substances of Human Origin ('SoHO') regulation.

Furthermore, EDQM also supports implementation by providing quality management training for professionals, a donor testing proficiency scheme, vigilance data analysis and guidance on topics not addressed in the current Union legislation such as emergency planning. This collaboration with EDQM has proven to be an essential element in the effective implementation of the Union rules and a key to promoting networking for the exchange of best practice among professionals with expertise in the SoHO area.

This action will build on the programmes established in the previous grant agreements and will introduce new actions to improve the safety, quality, and availability of SoHO.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the Council of Europe is the eligible legal entity to implement this action. EDQM has a crucial leadership, a convening and coordination role in global health, and in strengthening multilateral cooperation and in steering the world's preparation and response to public health emergencies. Therefore, EDQM is the sole entity with the required expertise and capacity to implement the action.

The starting date of the action may be set, where appropriate, prior to the signature of the contribution agreement and costs may be eligible before the submission of the proposal.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The activities of this action will focus on:

- a) maintaining/updating the sector-specific technical guidance documents for blood, for tissues and cells, for organs to support effective implementation of Union safety and quality requirements for all SoHO sub-sectors and incorporating guidance on emergency/crisis planning for all SoHO, including civil/military cooperation as appropriate. For blood, tissues and cells in particular, in line with the proposed SoHO regulation, develop an IT-tool where the state-of-play guidelines can be consulted, and host an IT-tool to assess risks of new preparations.
- b) supporting the exchange and implementation of good practices and the development of an action plan for achieving and maintaining sustainable supplies of SoHO particularly for:
 - i. plasma, in order to increase plasma collection in all Member States and therewith reduce their dependency on supply from third countries (covering different aspects like awareness building, emergency planning and structural collection/increase);

- ii. organs, tissues and cells, in order to maximize collection and availability of these SoHO for patients in all Member States (covering different aspects such as awareness building, emergency planning and structural collection/increase);
- c) aggregating and analysing vigilance data collected annually by the Commission from the Member States for blood and for tissues and cells and draft annual vigilance reports for each of those sub-sectors for validation by national competent authorities and publication by the Commission (integrate previously developed datasets, professional databases) and work from the Vigilance Expert Group, covering curating and governance of data);
- d) curating, aggregating, and analysing activity data collected annually by the Commission from the Member States for blood and for tissues and cells in accordance with the proposed SoHO Regulation. Provide guidelines and data sets to facilitate data collection and reporting by entities/establishments, prepare for EU-level reports;
- e) maintaining and organising further quality management courses and audits for blood and tissue establishments/banks (deliverable: updated programmes, courses held, number of blood/tissue establishments audited);
- f) maintaining an established scheme of proficiency testing (external quality control) for blood establishment laboratories that test donors for communicable diseases (deliverable: updated programme, number of blood establishment labs tested on proficiency).

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- a) common guidance for Union-based professionals and authorities on how to ensure safety and quality of SoHO;
- b) A plan for action to support national blood and transplant services with supply of plasma and organ/tissues/cells respectively. Reduced dependency on third countries for the supply of SoHO, in particular for plasma;
- c) a consolidated Union level view on supply and safety of different SoHO;
- d) increased capacities with professionals, in SoHO entities/establishments, as well as in testing laboratories, to comply with Union level requirements on safety and quality.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|--|-----------------------------------|--|
| HS-CA-24-58 | Q3/2024 | EUR 6 556 000 |
| Procedure type Indirect management | Implemented by DG SANTE | Entity Council of Europe - European Directorate for the Quality of Medicines & HealthCare |

HS-CA-24-51 Electronic Product Information

POLICY CONTEXT

Today, there is no harmonised regulatory-approved electronic product information on medicines in Europe. The development and implementation of electronic product information is a legislative action of the Pharmaceutical Strategy for Europe¹⁶³.

The Pharmaceutical Strategy for Europe refers the role for electronic product information ('ePI') to facilitate the delivery of information on medicines to healthcare professionals and patients in the EU's multilingual environment and support wider availability of medicines across Member States.

ePI is expected to:

- a) expand access to information on medicines (incl. to users with diverse capabilities);
- b) open access to regulatory-approved information;
- c) support mitigation of shortages and address access issues particularly in smaller markets;
- d) provide simplification of administrative procedures and faster update of information on medicines;
- e) enhance interoperability with other Union and global initiatives like the EHDS (ePrescription, electronic Health Record), Union telematics projects, global standards.

The action is intended to follow up the project financed under the 2021 and 2022 EU4Health work programmes, in the framework of the Contribution Agreement (SANTE/2021/SI2.869573&SI2.869590) signed by the Commission and the European Medicines Agency (EMA). The above-mentioned Contribution Agreement established the necessary tooling, guidance and planning to perform a pilot study for ePI of some real cases of medicines for centrally and nationally authorised medicines, to initiate the pilot study and analyse its preliminary results.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, EMA is the eligible legal entity to implement this action. EMA plays a crucial role in supporting the Union and Member States in response to the Pharmaceutical Strategy for Europe.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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, (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to move from pilot-to Implementation phase.

In particular, this action will include the following activities:

¹⁶³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pharmaceutical Strategy for Europe. [COM\(2020\)761 final](#).

- a) development of functionalities to cater for specific Member State requirements: linguistic review and upload of translations, support mutual recognition and decentralised procedures;
- b) ePI on a public website: support outreach, communication and Member State adoption;
- c) resource permitting improvements in user interface/experience; versioning; greater integration into IT systems including Substances, product Organisation and Referential (SPOR) master data systems¹⁶⁴; optimisation of import functionality.

EXPECTED RESULTS AND IMPACTS

The expected results are the following:

- a) a positive user experience for marketing authorisation applicants, giving pharmaceutical industry stakeholders the necessary evidence and confidence to invest resources and effort to support ePI implementation;
- b) a smoothly running pilot, where any issues that arise can be managed and resolved in a timely manner, contributing to stakeholder confidence in the product;
- c) enable access to information in the Union’s multilingual environment, support wider availability of medicines across the Union, help mitigate shortages;
- d) forward momentum of the ePI initiative, building on what has already been achieved by the EMA, National Competent Authorities and the Commission;
- e) high external visibility – high interest for patients, healthcare professionals, industry, EU/EEA countries, international level (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

| Topic/sub-topic | Estimated launch date | Budget |
|--|------------------------------|--|
| HS-CA-24-51 | Q2-Q3/2024 | EUR 1 700 000 |
| Procedure type | Implemented by | Type of applicants targeted |
| Indirect management - contribution agreement | DG SANTE | Decentralised Agency (European Medicines Agency) |

¹⁶⁴ Substance, product, organisation and referential (SPOR) master data. ([EMA](#)).