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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 2023**

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## INTRODUCTION

On 24 March 2021, Regulation (EU) 2021/522 of the European Parliament and of the Council<sup>1</sup> 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 and on 14 January 2022 the Commission adopted the 2022 work programme. Two amendments have been adopted on 12 April 2022<sup>2</sup> and on 25 July 2022<sup>3</sup> which clarified the appropriate management mode for pillar assessed organisations.

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

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<sup>1</sup> 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).

<sup>2</sup> C (2022) 2470 final.

<sup>3</sup> C (2022) 5436 final.

Agency (EMA)<sup>4</sup> and the European Centre for Disease Prevention and Control (ECDC)<sup>5</sup> and, once adopted, will support the implementation of the Health Union Package, in subsequent work programmes.

The EU4Health work programme for 2023 consists of four overarching ‘strands’: (1) crisis preparedness; (2) health promotion & disease prevention; (3) health systems & healthcare workforce; and (4) digital. Cancer is considered as a transversal strand.

In particular the EU4Health work programme 2023 will also address health-related urgencies due to the COVID-19 pandemic and Russia’s unjustified and unprovoked war against Ukraine, it will support emerging policy initiatives by President von der Leyen<sup>6</sup> in the State of the Union Address and in the associated Letter of Intent 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 recently adopted proposal for a Council recommendation on a new EU approach on cancer screening<sup>7</sup>.

In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, the EU4Health Programme will be implemented in overall consistency, synergy and complementarity with other Union programmes<sup>8</sup>, policies, instruments and actions, such as Horizon Europe. Through its EU Mission on Cancer<sup>9</sup>, Horizon Europe will contribute to the implementation of some of the Europe’s Beating Cancer Plan flagships and actions.

This work programme sets out objectives and actions, including the resource allocation, for the implementation of the EU4Health Programme in 2023. In pursuing those actions, the needs of people in vulnerable situations, the reduction of inequalities in the provision of healthcare, in particular in rural and remote areas, including in the outermost regions<sup>10</sup>, for the purposes of achieving inclusive growth and a gender sensitive approach will be considered where relevant as well as the health consequences of Russia’s unjustified and unprovoked war against Ukraine.

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

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<sup>4</sup> 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).

<sup>5</sup> 2020/0320(COD), not yet published in the Official Journal.

<sup>6</sup> [State of the Union \(europa.eu\)](https://www.europa.eu).

<sup>7</sup> COM(2022) 474 final.

<sup>8</sup> For example: Digital Europe Programme, Horizon Europe, the Union Civil Protection Mechanism and in particular its European reserve of additional capacities (the RescEU reserve), the Emergency Support Instrument, the ESF+, the ERDF, the Recovery and Resilience Facility, and Erasmus+, and the European Solidarity Corps Programme.

<sup>9</sup> European Mission – Cancer – Implementation Plan.

[https://ec.europa.eu/info/sites/default/files/research\\_and\\_innovation/funding/documents/cancer\\_implementation\\_plan\\_for\\_publication\\_final\\_v2.pdf](https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/cancer_implementation_plan_for_publication_final_v2.pdf).

<sup>10</sup> EU outermost regions located in the Atlantic and Indian Oceans, in the Caribbean basin and in Latin America.

programme ‘Member States’ authorities’ means ‘competent authorities responsible for health in the Member States or in third countries associated to the EU4Health programme’.

## LEGAL BASIS

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

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 on the establishment of a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014, and in particular Article 17(2) thereof.

## BUDGET OVERVIEW FOR 2023

On the basis of the objectives defined in Regulation (EU) 2021/522, this work programme contains the actions to be financed and their total budget (Table 1). The budget breakdown for 2023 is indicated in Table 2.

**TABLE 1: BUDGET LINES**

<b>BUDGET LINES</b>	<b>2023 (in EUR)</b>
06 06 01 <sup>11</sup>	715 121 072
<b>TOTAL</b>	715 121 072

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.

Grants<sup>12</sup> are financial contributions by way of donation by the Commission in order to finance: (a) an action intended to help achieve a Union policy objective (action grants) or (b) the functioning of a body, which has an objective forming part of, and supporting, a Union policy or an aim of general interest for the Union (operating grants).

<sup>11</sup> Without EFTA contributions, estimated amounts for 2023 is EUR 20 666 999.

<sup>12</sup> Articles 2(33) and Article 180(2) of Regulation (EU, Euratom) 2018/1046.

Procurement<sup>13</sup> 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**

<b>FUNDING</b>	<b>2023 Budget</b> (in million EUR)
<b>Direct management</b>	<b>604.69</b>
of which Grants	428.26
of which Procurement	176.43
<b>Indirect management</b> (contribution agreements)	<b>131.10</b>
<b>TOTAL</b>	<b>735.79</b>

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

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

The Commission delegates powers<sup>14</sup> to implement actions to the Health and Digital Executive Agency ('HaDEA')<sup>15</sup>.

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

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<sup>13</sup> Article 2(49) of Regulation (EU, Euratom) 2018/1046.

<sup>14</sup> Article 69 of Regulation (EU, Euratom) 2018/1046.

<sup>15</sup> For actions implemented under indirect management, these are subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

**TABLE 3: BUDGET BY ACTION AREAS**

<b>STRANDS &amp; AREAS OF ACTION</b>	<b>2023 budget (in million EUR)</b>
<b>1. CRISIS PREPAREDNESS (CP)</b>	<b>358.40</b>
HERA <sup>16</sup>	242.75
IMPROVING AND STRENGTHENING NATIONAL SURVEILLANCE SYSTEMS	97.6
STRENGTHENING THE EU EARLY WARNING AND RESPONSE SYSTEM AND NATIONAL ALERT AND INFORMATION SYSTEMS (EWRS) <sup>17</sup>	2.0
EUROPEAN IMMUNIZATION AGENDA <sup>18</sup>	2.0
SUPPORT THE SET-UP ESTABLISHMENT AND OPERATION OF EU REFERENCE LABORATORIES	8.2
ADVISORY COMMITTEE SET - UP TO DEAL WITH EMERGENCIES	0.45
RISK ASSESSMENTS FOR CHEMICAL, ENVIRONMENTAL AND CLIMATE THREATS DRAWN UP WITHIN AGENCIES <sup>19</sup>	0.6
INTEGRATED SURVEILLANCE SYSTEMS ON ANTIMICROBIAL RESISTANCE AND ANTIMICROBIAL USE	0.5
CRISIS PREPAREDNESS IN UKRAINE AND NEIGHBOURING COUNTRIES <sup>20</sup>	4.3
<b>2. HEALTH PROMOTION &amp; DISEASE PREVENTION (DP)</b>	<b>33.54</b>
TOBACCO CONTROL POLICIES	4.0
PREVENTION OF NON-COMMUNICABLE DISEASES (NCDs) – CHRONIC RESPIRATORY DISEASES, MENTAL HEALTH, DEMENTIA	18.36
OPERATING GRANTS	9.0
SUPPORT TO HEALTH POLICY PLATFORM, SCIENTIFIC COMMITTEES, AND EXPERT GROUPS, AND SUPPORT TO EUROPEAN CLIMATE AND HEALTH OBSERVATORY	2.18
<b>3. CANCER (CR)</b>	<b>187.3</b>
CANCER PREVENTION	1.5
EU NETWORK OF COMPREHENSIVE CANCER INFRASTRUCTURES	130.5

<sup>16</sup> Including CP-CA-23-09, CP-CA-23-25.

<sup>17</sup> CP-CA-23-03.

<sup>18</sup> CP-CA-23-06.

<sup>19</sup> CP-CA-23-07.

<sup>20</sup> CP-CA-23-04.



IMPLEMENTATION OF CANCER SCREENING PROGRAMMES	38.5
MENTAL HEALTH AND CANCER	10.0
QUALITY OF LIFE OF CANCER SURVIVORS	1.5
REDUCING CANCER INEQUALITIES <sup>21</sup>	2.5
IMPLEMENTATION OF STRATEGIC AGENDA FOR MEDICAL IONISING RADIATION	2.8
<b>4. HEALTH SYSTEMS &amp; HEALTHCARE WORKFORCE (HS)</b>	<b>118.42</b>
REFORMING AND STRENGTHENING HEALTH SYSTEMS <sup>22</sup>	8.7
ENHANCING EUROPEAN REFERENCE NETWORKS	83.4
STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS	1.4
IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES	8.25
IMPLEMENTATION OF PHARMACEUTICALS LEGISLATION AND PHARMACEUTICAL STRATEGY FOR EUROPE <sup>23</sup>	8.17
IMPLEMENTATION OF THE HEALTH TECHNOLOGY ASSESSMENT REGULATION	3.00
IMPLEMENTATION OF THE CROSS-BORDER HEALTHCARE DIRECTIVE	0.5
GLOBAL HEALTH	5.0
<b>5. DIGITAL (DI)</b>	<b>26.0</b>
EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE; PRIMARY USE OF DATA	19.5
EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE; SECONDARY USE OF DATA	6.5
<b>6. OTHER ACTIONS</b>	<b>12.12</b>
COMMUNICATION ACTIVITIES	3.67
RECURRENT IT ACTIVITIES	5.5
OTHER ACTIVITIES	2.95

<sup>21</sup> Including CR-CA-23-42.

<sup>22</sup> Including HS-CA-23-45-01; HS-CA-23-45-02; HS-CA-23-70-01; HS-CA-23-70-02.

<sup>23</sup> Including HS-CA-23-52; HS-CA-23-57.

## **ELIGIBILITY, SELECTION AND AWARD CRITERIA FOR 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 bodies<sup>24</sup>.

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

- (a) relevance to the priorities of the call for proposals;
- (b) quality of the proposed action;
- (c) impact of the proposed action.

Grants shall involve co-financing<sup>25</sup>. The maximum possible rate of Union co-financing is up to 60% of the total eligible costs of the action, unless specified otherwise in the specific calls for proposals. In cases of exceptional utility, the Union contribution may be increased up to 80% of the total eligible costs<sup>26</sup>. In the case of European Reference Networks (ERNs), the Union contribution may be up to 100% of eligible costs in accordance with Article 8(4) of Regulation (EU) 2021/522.

Exceptional utility assessment and ranking of proposals shall be done in accordance with the criteria described in the calls for proposals.

## **PROGRAMME PERFORMANCE MONITORING AND INDICATORS**

The EU4Health Programme has in place a sound performance framework, developed by the Commission and stemming 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 monitoring and evaluation framework of the EU4Health Programme. For each action, meaningful indicators will be included and beneficiaries will collect data for measuring and monitoring the progress of implementation and for highlighting the key results achieved. Data needs to be available for these indicators on a regular basis and

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<sup>24</sup> Article 198(5) and (6) of Regulation (EU, Euratom) 2018/1046.

<sup>25</sup> Article 190(1) of Regulation (EU, Euratom) 2018/1046.

<sup>26</sup> Article 8(3) of Regulation (EU) 2021/522.

must be of sufficient quality and reliability; given limited resources, the collection of such data shall also be cost-efficient.

## A. GRANTS

### ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

#### 1. CRISIS PREPAREDENESS (CP)

#### **CP-g-23-01 Direct grants to Member States' authorities: improving and strengthening national surveillance systems (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU<sup>27</sup>)**

##### POLICY CONTEXT

The COVID-19 pandemic has highlighted a number of shortcomings in the Member States' surveillance systems. The ongoing transition to management of the COVID-19 pandemic, if undertaken without a profound improvement of pre-existing surveillance infrastructures, puts the Member States and the EEA countries at risk of facing similar challenges, as those observed at the beginning of the pandemic. This justifies a number of the Commission's concerted actions to support Member States in strengthening their surveillance systems.

Among the most relevant challenges observed during the COVID-19 pandemic, there were infrastructural issues that should be addressed to ensure sustainable and fit-for-purpose surveillance systems. Some of the main issues were that the epidemiological data submitted to the Commission were often delayed and not easily comparable across Member States, and some important health system information was missing or difficult to obtain. For instance, there is a lack of full digitalisation of national surveillance systems, as paper notification is still used at the subnational levels. There is a need to extend and apply to other notifiable diseases the new epidemiologic models, such as the molecular and genomic typing for surveillance used in COVID-19 laboratory surveillance. The epidemic intelligence needs to broaden its data sources and methods, chart new territories, such as big data and artificial intelligence, and make use of existing intelligence tools, such as Epidemic Intelligence from Open Sources (EIOS), while ensuring that more traditional indicator-based, and molecular and genomic typing data are not neglected.

To support the One Health approach, and work on detection of epidemic-prone agents, there is a need to enlarge the scope of public health surveillance, extending to veterinary and environmental surveillance sources for vector borne and zoonotic diseases (established and emerging). Innovative solutions for new surveillance methods could be the use of electronic health records and mobile health (m-health) applications as well as data from other existing sources, such as passenger locator forms, that may hold huge potential for infectious disease surveillance.

According to the ECDC long-term surveillance framework (LTSF) 2021-2027 vision, the EU/EEA surveillance of infectious diseases should be founded on strong harmonised national

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<sup>27</sup> 2020/0322 (COD), not yet published in the Official Journal.

surveillance systems, encompassing an optimal mixture of data sources and on state-of-the-art technology. This would allow to generate a continuous, automated, integrated surveillance and, where required, real-time digital data stream that provides the right information where and when it is needed to most timely and effectively fight cross-border threats to public health from infectious diseases.

The COVID-19 pandemic response has prompted a digital revolution in many surveillance systems. The EU and national priorities in fostering integration, digitalisation and establishment of real-time surveillance are handled by post-COVID-19 surveillance contracts and the preparatory Joint Action on integrated surveillance (JA UNITED4Surveillance<sup>28</sup>) financed by the 2021 EU4Health work programme. JA UNITED4Surveillance aims to support Member States in the implementation of digitalised, integrated surveillance systems at EU and national level, to ensure better detection of early epidemiological signals for accurate risk assessment and response.

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.

It supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b) 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**

The aim of the direct grant is to support Member States to improve their surveillance system in line with and building on the outcomes of the JA UNITED4Surveillance.

The activities that could be carried out towards scaling up national surveillance systems aim to facilitate the required national capacity building for the development of interoperable, reliable and modern national surveillance systems. The action will be driven by digital transformation, making use of relevant available health data and public health research results.

This action will cover the following activities:

**Assessment of Member State surveillance systems:** Following an initial assessment of the state of digitalisation and integration of surveillance systems in each Member State, gaps and needs for support shall be identified. The findings should support subsequent targeted investments for sustainable developments in the following areas:

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<sup>28</sup> CP-g-02.1.1 Direct grants to Member States' authorities: Union and national surveillance systems.

- a) **Infrastructure development:** this activity aims at upgrading or developing surveillance information management systems to integrate the different components of surveillance systems for the reporting of cases and relevant information to local and national public health authorities. For example, such information system would facilitate the (re-) establishment or further strengthening of integrated surveillance systems for monitoring trends of respiratory infections in the Union, for rapidly detecting upsurges that could be related to the emergence of a new SARS-CoV-2 variant or to influenza pandemic prone strains, and enabling forecasting in order to support containment and mitigation measures and to trigger healthcare system and EU preparedness. These digital data reporting systems that guide the entire surveillance process should be customisable to adapt to different surveillance objectives and diseases under surveillance.

This action could facilitate the set-up or strengthening of national early warning and response systems, linking existing other alert and information systems for the detection of new emergent threats, including integration of animal and environmental health data sources and to facilitate the reporting to the EU EWRS, including linking national systems to the future HERA IT Platform. Infrastructure development projects will also allow Member States to promote interoperability of data across different information systems, to facilitate data linkage with external databases, if deemed relevant (e.g. with immunisation information systems, mortality databases, screening programmes databases), and to integrate advanced data validation and analysis tools benefitting from new technologies, such as artificial intelligence. Such customisable surveillance systems would therefore cover a range of diseases which are part of the EU surveillance notifiable diseases, from epidemic-prone diseases to diseases that are part of prevention and control programmes (e.g. AIDS, tuberculosis and vaccine-preventable diseases);

- b) **Capacity building:** Member States will be supported in establishing training programmes targeting surveillance at the different levels of the healthcare systems. The training will cover the various surveillance methods developed or upgraded based on the results of the JA UNITED4Surveillance, this grant, and other activities at national and EU level. A training-of-trainers module will also be included to strengthen national and subnational surveillance for longer-term capacity building sustainability. The training activities will include technical and legal background knowledge on the implementation of integrated surveillance, including compliance with Regulation (EU)2016/679<sup>29</sup>;
- c) **Piloting, implementation and uptake according to Member State priority needs:** Newly established or upgraded integrated surveillance systems will be piloted at national level to test and improve functionality, as well as to demonstrate end-to-end interoperability. The innovative approaches for piloting integrated surveillance implemented under the JA UNITED4Surveillance as preparatory actions could be

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<sup>29</sup> Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

continued, extended at national and at EU level. Consequently, integrated surveillance pilots could be implemented for routine use, part of the national surveillance system procedures including data transfer to ECDC.

This action will extend the support for setting up the EU One Health approach, i.e. integration and linkage with veterinary surveillance will also provide an early warning system in relation to zoonotic risks to public health.

The activities will complement the JA UNITED4Surveillance in particular the assessment of the Member States and EEA countries digital readiness for setting up integrated surveillance systems at national and regional level. This also includes the identification of legal and technical barriers to using electronic health data for integrated surveillance and an inventory of good practices to overcome these barriers.

#### **EXPECTED RESULTS AND IMPACT**

National surveillance systems will be strengthened and better interoperable with the EU surveillance system hosted by ECDC, complementing the outcomes of JA UNITED4Surveillance.

Early warning systems at national level will be set-up or reinforced to detect emergent infectious diseases, linking existing alert and information systems, including integration of animal and environmental health data sources and to facilitate the reporting to the EU early warning and response system (EWRS) and the future HERA IT platform, where possible.

National capacity building, linkage of routine surveillance and electronic health data sources will allow scaling up integrated surveillance and improve outbreak detection. Ultimately, these actions, based on the national integrated surveillance evaluation and plans, will support EU and national surveillance systems to ensure a rapid response to cross-border threats to health.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants - CP-g-23-01	Q1-Q2/2023	EUR 97 300 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States in accordance with Article 195, first paragraph, point (c) of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

## 2. CANCER (CR)

### 2.1 CANCER SCREENING PROGRAMMES

#### **CR-g-23-38 Direct grants to Member States' authorities: Implementation of cancer screening programmes**

##### **POLICY CONTEXT**

Cancer prevention, screening and early detection offer the best chance of beating cancer and saving lives. The 2003 Council Recommendation on Cancer Screening<sup>30</sup> in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. As of 2020, 25 Member States had introduced population-based screening programmes in their National Cancer Control Plans for breast cancer, 22 countries for cervical cancer and 20 for colorectal cancer. On 20 September 2022, the Commission adopted a proposal for a new Council Recommendation<sup>31</sup> to ensure that the latest available scientific evidence is reflected in the Council Recommendation, including the extension of screening to prostate, lung, and gastric cancers. Member States will benefit from EU support in fully implementing population-based cancer screening programmes for breast, colorectal and cervical cancers, with EU guidelines and quality assurance schemes, such as the Commission Initiatives on Breast and Colorectal Cancer<sup>32</sup>, as well as guidelines and quality assurance schemes on cervical cancer. In addition, this action will support feasibility testing, planning, and piloting of implementation of screening programmes for the three newly recommended cancers i.e. for lung, prostate and gastric cancers. Overall, this action will contribute also to reducing inequalities in access and quality of screening, diagnoses and care services between the Member States<sup>33</sup>.

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 joint action will support the policy objective of reducing the burden of cancer 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 (i), of Regulation (EU) 2021/522.

##### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this joint action is to support the full implementation of cancer screening for breast, colorectal and cervical cancers, in line with the Commission Initiatives on Breast and

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<sup>30</sup> Council Recommendation of 2 December 2003 on cancer screening (OJ L 327, 16.12.2003, p.34-38).

Proposal for a Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening (COM(2022) 474 final).

<sup>32</sup> <https://healthcare-quality.jrc.ec.europa.eu>.

<sup>33</sup> Complementarity with funding under ESF will be ensured to avoid duplication of same regions/countries.



Colorectal cancers. The action responds to the ‘Call to Action’<sup>34</sup> issued under the Czech Presidency of the Council as part of the Presidency conference on “Modern Cancer Control: Saving Lives through Smart Solutions”.

This action will cover the following activities:

- a) feasibility testing, planning, piloting of implementation of cancer screening for prostate, lung and gastric cancers to facilitate a step-wise approach for roll-out and full implementation;
- b) identification of and addressing barriers and facilitators for the utilisation of screening services within different health systems in the Member States;
- c) structured and sustainable exchange of experiences and best practices between the Member States including the development of quality standards for piloting and rolling out modifications by multi-professional teams involving also peer support and addressing training needs;
- d) supporting the further development of the European Cancer Information System and European Cancer Inequalities Registry regarding cancer screening indicators in particular to prepare for initial reporting requirements<sup>35</sup>;
- e) identification and assessment of upcoming innovative methods and practices in screening areas covered under the proposal for a Council Recommendation and scanning the developing evidence in other areas currently not covered, which may facilitate future extension of screening and/or early diagnosis to other types of cancers;
- f) addressing specific challenges posed to persons with particular needs in terms of accessing cancer screening including people living in rural or remote geographical areas, persons with disabilities, or who suffer from stigma and discrimination.

## EXPECTED RESULTS AND IMPACT

The expected results will be to streamline and support Member States’ efforts to implement the proposed Council Recommendation on cancer screening at national level, once adopted, thereby reducing inequalities and variation in terms of availability and access to high quality cancer screening programmes and based on EU guidelines and quality assurance schemes. The action will prepare and support the monitoring of the implementation of the proposed Council Recommendation and develop a structured and sustainable mechanism for exchange of best practices between the Member States.

The joint action will link to the work of the EU Knowledge Centre on Cancer and ongoing EU funded actions under the Europe’s Beating Cancer Plan and the Horizon Europe Mission on Cancer, such as the “direct grant to IARC to update the European guidelines for quality assurance in cervical cancer screening” (EU4Health WP2022 - CR-g-22-09.04<sup>36</sup>), the “call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at EU level” (EU4Health WP2022 – CR-g-22-

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<sup>34</sup> [Call-to-Action\\_CZ-PRES-Expert-Conference-on-Oncology.pdf \(mzcr.cz\)](#).

<sup>35</sup> EU4Health 2021 work programme - DP/C-g-09.2.2 (CanScreen-ECIS); EU4Health 2022 work programme - CR-g-22-10.01/03, CR-g-22.10.02.

<sup>36</sup> [https://health.ec.europa.eu/system/files/2022-07/com\\_2022-5436\\_annex2\\_en.pdf](https://health.ec.europa.eu/system/files/2022-07/com_2022-5436_annex2_en.pdf).

09.01/02/03<sup>37</sup>) and projects funded under the call topic “Develop new methods and technologies for cancer screening and early detection (HORIZON-MISS-2021-CANCER-02-01<sup>38</sup>).

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants - CR-g-23-38	Q2-Q3/2023	EUR 31 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States’ authorities

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<sup>37</sup> Idem.

<sup>38</sup> <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-miss-2021-cancer-02-01>.

## 2.2 EU NETWORK OF COMPREHENSIVE CANCER INFRASTRUCTURES

### **CR-g-23-40.1-2 Direct grants to Member States' authorities: to establish an EU network of Comprehensive Cancer Infrastructures and new networks of expertise on cancers and cancer conditions**

#### **POLICY CONTEXT**

The European Guide on Quality Improvement in Comprehensive Cancer Control<sup>39</sup> recommends as a priority the establishment of Comprehensive Cancer Care Networks, and likewise the Horizon Europe Cancer Mission Board recommends in its report the establishment of a network of Comprehensive Cancer Infrastructures in all Member States and the networking of these infrastructures at EU level.

One of the flagship initiatives of Europe's Beating Cancer Plan is the establishment by 2025 of an EU Network of Comprehensive Cancer Infrastructures, linking recognised Comprehensive Cancer Centres, 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.

Under the EU4Health 2021 work programme<sup>40</sup> two preparatory Joint Actions have been launched to develop the concepts for an EU Network of Comprehensive Cancer Infrastructures (national centres or networks) and for new cancer networks of expertise<sup>41</sup>. This action aims to implement the concepts developed and upscale the initial piloting work<sup>42</sup>.

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

The two new joint actions referred to in this action, support the policy objective of reducing the burden of cancer and implement 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 (i), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

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<sup>39</sup> [https://www.cancercontrol.eu/archived/uploads/images/Guide/pdf/CanCon\\_Guide\\_FINAL\\_Web.pdf](https://www.cancercontrol.eu/archived/uploads/images/Guide/pdf/CanCon_Guide_FINAL_Web.pdf).

<sup>40</sup> [https://health.ec.europa.eu/system/files/2022-07/com\\_2022-5436\\_annex1\\_en.pdf](https://health.ec.europa.eu/system/files/2022-07/com_2022-5436_annex1_en.pdf).

<sup>41</sup> DP/C-g-10.1.2 and 3.

<sup>42</sup> Joint Action on Networks of Expertise (JANE) and Joint Action on network of Comprehensive Cancer Centres (CRANE).

The aim of these two joint actions is the co-creation of an EU Network of (national level) Comprehensive Cancer Infrastructures, avoiding potential unnecessary duplication of activities. They will cover the following activities:

- a) Support to the establishment or improvement of national Comprehensive Cancer Centres or Networks;
- b) Establishment of new cancer (reference) networks of expertise focusing on cancers and cancer conditions not yet covered by established ERNs building on the preparatory work and conceptualisations developed through the JANE Joint Action and development of potential additional networks which will also ensure synergies and interoperability with the existing data infrastructure for ERNs;
- c) Integration of the new (reference) networks of expertise and the established ERNs on rare cancers.

#### **EXPECTED RESULTS AND IMPACT**

The joint actions will support the establishment of an EU Network of Comprehensive Cancer Infrastructures or Networks, that is expected to improve early detection of cancers in the general population, and to enable cancer patients and survivors to benefit from better access to all steps of cancer care and high-quality cancer research. This would include better access to diagnosis, treatment, rehabilitation, palliative care and support to survivorship, and to innovative approaches that will have the potential to be developed in the future. The establishment of the EU Network will also help with patient mobility to ensure adequate treatment for patients with complex conditions.

The joint actions will establish and integrate new cancer (reference) networks of expertise with the established ERNs on rare cancers.

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

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants Two joint actions: Sub-topic CR-g-23-40.1 (EU Network of Comprehensive Cancer Centres)	Q2-Q3/2023	EUR 90 000 000
Sub-topic CR-g-23-40.2 (new networks of expertise)		EUR 40 500 000

<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grants to Member States (two joint actions) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

### 3. HEALTH SYSTEMS & HEALTHCARE WORKFORCE (HS)

#### 3.1 ENHANCING EUROPEAN REFERENCE NETWORKS

##### **HS-g-23-49 Direct grants to European Reference Networks (ERNs): support for the coordination, management, and operational activities of the ERNs**

###### **POLICY CONTEXT**

The ERNs were established in 2017 in accordance with Article 12 of Directive 2011/24/EU of the European Parliament and of the Council<sup>43</sup> in the field of rare or low-prevalence complex diseases.

Currently there are 24 virtual networks connecting specialised healthcare providers across the Union.

A direct (action) grant was provided under the 2022 work programme<sup>44</sup> to ERNs to ensure business continuity until 2023.

This action ensures support for the period 2023-2027 for the functioning and enhancement of the system of ERNs. It will enable rare disease patients and their health professionals to benefit from the pooling of expertise, knowledge and resources at EU level and to receive the appropriate diagnosis and treatment as well as enhance knowledge generation, training and research in the area of rare diseases. It will provide support to the 24 ERNs including their coordination centres for the coordination, management and operational activities of the ERNs, and facilitate the long-term sustainability of ERNs and their better integration into national health systems. It will also support activities connecting Ukrainian competent authorities and healthcare units to the ERNs, taking into consideration the experience of the Rare Diseases Hub Ukraine.

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 ERNs, which solely have the required competence and responsibility to implement the action.

In accordance with Article 193(2), point (a), of Regulation (EU, Euratom) 2018/1046 and Article 5(7) and Article 14 of Regulation (EU) 2021/522, the starting date of actions may be set, where appropriate, prior to signature of the grant agreement and costs may be eligible before submission of the proposal.

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), (g) and (i), of Regulation (EU) 2021/522.

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<sup>43</sup> 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).

<sup>44</sup> HS-g-22-16.01.

## **OBJECTIVES, SCOPE AND ACTIVITIES**

The proposed action will support coordinating centres and members of the 24 ERNs for the coordination, management and operational activities (including integration of new members and affiliates partners).

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

- a) coordination, management and operational activities of ERNs;
- b) knowledge generation and exchanges of best practice concerning diagnosis and the delivery of high-quality and cost-effective healthcare for patients with rare or low prevalence diseases;
- c) dissemination of generated knowledge on rare or low prevalence diseases to a wider audience;
- d) coordination of and support for development and updating of clinical practice guidelines and other clinical decision support tools;
- e) coordination, promotion, and management of professional training activities, including through the ERN virtual academy;
- f) coordination, promotion, management and support for virtual discussions on clinical cases through the Clinical Patient Management System IT tool, including contribution to its development;
- g) coordination of and support for functioning of ERN registries, including joining<sup>45</sup> of the European Platform on Rare Disease Registration (EU RD Platform)<sup>46</sup> in line with their technical specifications;
- h) coordination, management and support activities for long-term sustainability of the ERN system and better integration of ERNs into national systems;
- i) support to collaboration activities to effectively link Ukrainian competent authorities and healthcare units to the ERNs, contributing to capacity building and best practice sharing with Ukraine, building on the experience of the Rare Diseases Hub Ukraine.

## **EXPECTED RESULTS AND IMPACT**

This action will ensure continuity for ERNs's coordination and operation for the period 2023-2027 and will support the provision of specialised healthcare for rare diseases, development of new guidelines, build evidence of best practices, develop educational programmes and training, set the research agenda in collaboration with stakeholders including patient representatives, and share knowledge through participation in virtual multidisciplinary teams. It will also support the use of the IT tool for virtual discussions of clinical cases, its adaptation to specific needs of ERNs and the functioning of ERNs registries. In addition, the action will support ERNs towards their integration into national health systems and future sustainability.

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<sup>45</sup> This will ensure the inclusion of individual registries and the ERN central registry in the EU RD Platform and allow the use of SPIDER services for patient pseudonymisation, data linkage and data transfer in the local registries/data source.

<sup>46</sup> [https://eu-rd-platform.jrc.ec.europa.eu/\\_en](https://eu-rd-platform.jrc.ec.europa.eu/_en).

This action will help in pooling knowledge, expertise and resources for the benefit of patients suffering from rare diseases in the Union and related health professionals, including by promoting common standards and tools, allowing for better sharing and interoperability of (anonymised) rare disease patients' data through the EU RD Platform, as an opportunity for research projects.

The action will also support the creation of a national focal point for Ukrainians who need specialised medical support for their rare and/or complex conditions and develop pathways for patients and their families.

The use of multiannual direct grants for ERNs will streamline the funding of ERNs (currently provided from different funding instruments) and reduce the administrative burden for ERNs.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call opening</b>	<b>Budget</b>
Direct grant – HS-g-23-49	Q1/2023	EUR 77 400 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grants to bodies identified by the basic act in accordance with Article 195, first paragraph, point (d), of Regulation (EU, Euratom) 2018/1046	HaDEA	Coordinating centres and members of the 24 established ERNs



## **ACTIONS WITH A COST BELOW EUR 20 000 000**

### **1. CRISIS PREPAREDNESS (CP)**

#### **CP-g-23-13 Call for proposals to support access to medical devices for cross border health threats (HERA)**

##### **POLICY CONTEXT**

HERA is responsible for improving preparedness and response to serious cross-border threats in the area of medical countermeasures (MCM), notably by promoting advanced research and development of medical countermeasures and related technologies; and addressing market challenges and boosting the EU's open strategic autonomy in the medical countermeasures production. Medical devices and in vitro diagnostic medical devices to be used in the context of preparedness and response to cross-border health threats have a fundamental role in saving lives. By this action, HERA will support and ensure the availability of healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

The use of certain medical devices, including in vitro diagnostic medical devices, encounters issues of access by patients or continuity on the market because they are either targeted to a relatively small group of patients, or they are no longer considered advantageous to be kept on the market for commercial or other reasons. The lack of these medical devices and in vitro diagnostics can have an important impact for patients if they create a gap in the treatment, prevention or diagnosis of a cross-border health threat, particularly when there are limited or no alternatives are available in the market. Costs related to market access, in particular clinical evaluation and conformity assessment, often render the development of these devices economically not interesting. In case they are targeted to a relatively small group of patients or very specific intended purposes, innovation can lag behind comparing the advances made for other devices with wider applications.

This action supports the policy priority to increase patients' access to medical countermeasures 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, and supporting innovation regarding 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**

This action aims to support consortia that provide a platform of experienced regulatory, business planning, and device development services to help foster and guide the advancement of devices that can be used in case of serious cross-border health threats. This action does not cover orphan medical devices (medical devices for rare diseases), as these are addressed by a specific action within this work programme.

The consortia should facilitate the development, production, and distribution of these devices that can be used in case of serious cross-border health threats by providing services and

advice on: intellectual property, prototyping, engineering, laboratory and animal testing, grant-writing, and clinical investigation design.

A consortium should bring together different associations, organisations and/or institutions that can support medical device advancement through all stages of development: concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialisation.

To accomplish this work, a successful consortium should propose activities targeted to unite individuals, groups, or institutions to provide the following capabilities: knowledge of the clinical needs, business planning, conformity assessment requirements, intellectual property protections and other legal expertise, as well as scientific, engineering, pre-clinical, and clinical capabilities.

#### **EXPECTED RESULTS AND IMPACT**

This action is expected to result in an increased access to medical devices and in vitro diagnostic devices that are intended to treat, prevent or diagnose in relation to a cross-border health threat. The knowledge and information gathered through this action will also provide information on market gaps and recommendations on potential investments in the field of medical devices or in vitro diagnostic medical devices.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals - CP-g-23-13	Q2-Q3/2023	EUR 1 750 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals (action grants)	HaDEA	Scientific societies, academia, health authorities/institutions and NGOs, possibly also including SMEs active and with expertise in the area of the action

## **CP-g-23-18 Direct grants to Member States' authorities: to enhance, extend and consolidate wastewater surveillance for public health (HERA)**

### **POLICY CONTEXT**

HERA is responsible for the assessment of health threats and intelligence gathering in the area of medical countermeasures<sup>47</sup>. In order to do this, HERA will have dedicated capacities for horizon scanning, foresight, data analysis and market intelligence and will strengthen genome sequencing and environmental surveillance including wastewaters surveillance working closely with Member States, other Commission services and agencies.

Wastewater surveillance and the related epidemiological assessment emerged during the COVID-19 pandemic<sup>48</sup> as a tool to ensure timely and relevant intelligence gathering independent of behaviour (e.g. preparedness to test) and interventions (e.g. the quantitative assessment of virus particles in sewage revealed trends and its strong correlation with clinical cases<sup>49</sup>). This action will build on the activities started as part of the HERA incubator and the Commission Recommendation to support a consistent approach to the use of wastewater monitoring to track SARS-CoV-2 and its variants<sup>50</sup> and supported Member States with EUR 23<sup>51</sup> million funding (implemented through DG ENV) to accelerate the deployment of wastewater surveillance for COVID-19. In addition, DG JRC has initiated, stimulated and coordinated the authorities' network (national and international level including stakeholders), the development of a dashboard for exchanging of relevant information (DEEP) and organised the testing of samples from super-sites (used to compare and assess wastewaters of residential population vs. transportation hubs) in Lisbon, Madrid, Nicosia, Amsterdam, Frankfurt and Prague.

Since its roll-out, this joint effort has not only detected the emergence of the delta and omicron variants, but has provided additional insights and understanding how SARS-CoV-2 variants move across borders. Therefore, extending the support programmes set up under the HERA Incubator is essential to strengthen not only the detection and identification of SARS-CoV-2 variants in the Union but to also build on preparedness to other serious cross-border health threats such as those identified by HERA in its health threat prioritisation.

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 be best carried out by the Member States' authorities (namely

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<sup>47</sup> Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02.

<sup>48</sup> In line with research findings such as from the Horizon 2020 project VEO.

<sup>49</sup> As reported by several authorities dealing with wastewaters and based on public information available for instance [Correlation between Clinical and Wastewater SARS-CoV-2 Genomic Surveillance, Oregon, USA \(cdc.gov\)](https://www.cdc.gov/media/releases/2021/s0921-covid-wastewater.html).

<sup>50</sup> C(2021) 1925 final.

<sup>51</sup> The HERA, an initiative to better respond to variants of concern, included EUR 20 million from the Emergency Support Instrument (ESI) (direct grants to 26 of 27 Member States, leveraged by at least EUR 33.4 million from Member States) and EUR 3 million from NEAR for neighbouring countries.

public health authorities and those dealing with environmental surveillance) as they have the required legal and technical competences and responsibilities to implement the Union policies at national level.

This joint action supports the policy priority to strengthen the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-border threats to health particularly through supporting data gathering, information exchange and surveillance, as well as Health in all policies. 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) 2021/522) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

### **OBJECTIVES, SCOPE, ACTIVITIES**

Regular surveillance of wastewaters in combination with other indicators for the management of the COVID-19 pandemic can facilitate decision making as it allows among others things to follow-up any resurgences and emerging trends, as well as the reach of a peak wave, to confirm and complement the trends information coming from the lab-based positive cases, which is especially important in low-testing periods. As a consequence, wastewater surveillance has been included more systematically in the national surveillance strategies for the prevention and control of the COVID-19 pandemic. However, the level of maturity of the detection of the SARS-CoV-2 and its variants in sewage varies among Member States.

The main focus of this joint action is to support activities, to enhance and/or improve national public health wastewater surveillance capacities (including the EU outermost regions<sup>52</sup>) by strengthening knowledge exchange and sharing best practices. The activities of this joint action will target and bring together Member States' authorities such as public health ministries, health institutes and/or laboratories or other relevant structures at national, regional and/or local level and take into account evidence from relevant research. They should facilitate the integration and complementarity of wastewater surveillance with other surveillance systems with a clear public health perspective to strengthen preparedness and response to cross border health threats.

The activities to be covered by the joint action would include:

- (a) Definition of wastewater surveillance strategies. This will include for instance:
  - identification of priority pathogens and substances to be monitored (maintaining and extending the current SARS-COV-2 surveillance capacities, including those that were put in place through the emergency funding above mentioned to other priority threats<sup>53</sup>, including but not limited to Antimicrobial

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<sup>52</sup> In line with COM(2022) 198 final.

<sup>53</sup> Taking into account the HERA priority list of cross border health threats.

Resistance (AMR), vaccine-derived poliovirus variants and emergent pathogens to ensure better preparedness) in line with the HERA threat prioritisation;

- definition of objectives for the different priority threats identified, e.g. detecting emerging threats, monitoring on-going events, assessing trends;
- selection of strategic sampling location, collection, frequency and transportation;
- collection, interpretation and translation of results;
- modelling and integration into existing public health surveillance systems, including clinical surveillance;
- capacity development, exchange of experience, networking and training and development of educational materials for integration into (existing) diverse discipline programmed for target audiences (e.g. engineers, physicians, epidemiologists).

(b) Definition of technical procedures. This will include for instance:

- alignment of methods for e.g. detection, normalisation, data visualisation used by Member States to the extent needed;
- identification and exchange of best practices for various purposes and resource settings;
- enhancing comparability of data, interoperability of IT platforms, reporting and sharing of data with DEEP;
- capacity development, exchange of experience, networking and training.

(c) Establishment of governance framework:

- EU, European and international coordination;
- mapping of stakeholders and other actors and subsequent engagement;
- interaction and coordination with on-going activities at international level including with the WHO<sup>54</sup>;
- capacity development, exchange of experience, networking and training.

(d) Communication i.e. to the public, physicians, decision makers, technicians, engineers.

(e) Sustainability and financial viability of the wastewater surveillance.

The joint action will work in cooperation with HERA and DG JRC as well as with other relevant EU and global bodies e.g. the ECDC, the WHO, the UN Environment Programme (UNEP). Progress of this joint action should also serve to provide support to global actors and low- and middle-income countries that can benefit from the exchange of experience and lessons learned during this exercise. In addition, there will be coordination and duplications should be avoided with the EU sentinel system to be established under the procurement section (see action CP-p-23-20) for instance to submit samples to the system to be established in the context of an emergency.

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<sup>54</sup> Other stakeholders such as ECDC and the HERA laboratory network are expected to be involved for their knowledge and expertise where relevant.

## EXPECTED RESULTS AND IMPACTS

This joint action will result in increased surveillance capacities at national and EU level for (pandemic) preparedness and control of infectious diseases and AMR, and a better evidence-based integration of this type of surveillance into other types of routine surveillance by focusing on complementarities that environmental data can bring for instance to clinical surveillance.

Consolidating wastewater-based surveillance systems will add value beyond SARS-CoV-2 monitoring. The already implemented systems will be extended to provide possibilities for monitoring and early warning for future possible outbreaks of other pathogens of concern or the emergence of threats of environmental or chemical origin, whether intentional or not, affecting global security.

The approach could be particularly relevant to monitor pathogens of concern, AMR, and chemical substances such as pharmaceuticals. The monitoring of quantitative and qualitative changes and trends of pathogens/substances concentrations in wastewater can inform preparedness and response measures to certain cross-border health threats.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants - CP-g-23-18	Q1/2023	EUR 15 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

## CP-g-23-22 Direct grant to support the Africa Pathogen Genomics Initiative (PGI) (HERA)

### POLICY CONTEXT

The Council adopted on 20 May 2021 a decision to support the launch of negotiations for an international treaty on the fight against pandemics within the framework of the WHO. Such a treaty would support international efforts to reinforce global health security, on preparedness

and response to emerging serious cross-border health threats. One of HERA's core missions is contributing to reinforcing the global health emergency preparedness and response architecture.

Emerging serious cross-border health threats often have a global impact and therefore need to be looked at with a global perspective. Direct experience from the COVID-19 pandemic and data from countries show the need to strengthen the EU and global capacities against serious cross-border health threats. The pandemic has shown that threats arising in other parts of the world have a huge impact on health worldwide, including in the Union. Therefore, it is clear that the reinforcement of emergency preparedness and response at EU level needs to be coupled with strengthening it at global level.

One of the recurrent concerns with the emergence of COVID-19 variants has been the lack of capacity to detect emergent pathogens in certain regions, especially in Africa. Moreover, despite the possible transition of the COVID-19 pandemic to endemic phase and the overall stabilisation of the number of cases, countries in the African continent will continue to experience high frequency of outbreaks and the threat of infectious disease pathogens remains pervasive. This action targets support to increase sequencing capacities in different African regions to enable early detection of pathogens of pandemic potential and thus playing a critical role in reducing the clinical and economic burden of possible outbreaks at global level. The relevant body that is responsible for these activities in Africa is the Pathogen Genomics Initiative (PGI) of the African Centre for Disease Control and Prevention (Africa CDC) which has made tremendous progress towards a harmonised increase of capacities in the African continent.

Given that the Africa CDC has limited capacities in the field of grant management which could hamper the swift implementation of this action, the following two organisations have been identified as potential beneficiaries as they hold the expertise to manage the grant in collaboration with PGI and are currently doing so for other international donors:

- a) the Africa Public Health Foundation (APHF) which exists to forge partnerships and mobilize resources to support critical public health initiatives in service of the Africa Centres for Disease Control and Prevention;
- b) the African Society for Laboratory Medicine (ASLM) which is the first pan-African society for laboratory professionals, endorsed by the African Union (AU), coordinating relevant stakeholders to improve local access to world-class diagnostic.

Since these two organisations are the only ones on the ground with the capacity to deliver the expected results within the set timeframe, their participation is necessary for the achievement of the objectives of the grant pursuant to Article 13 (2) and (5) of Regulation (EU) 2021/522 they are considered eligible legal entities.

Their participation is essential to ensure that the action can be implemented in the African regions, and this is vital to counter the spread of the risk and to protect the health of the people in the Union, particularly in case of new variants of SARS-CoV-2. This action will

also ensure the consolidation of capacities for other cross-border health threats<sup>55</sup>. Thus, incurred costs by the beneficiaries are also eligible in line with Article 14(3) of Regulation (EU) 2021/522.

This action constitutes a direct grant and will be awarded without a call for proposals on the basis of the exception referred to in Article 195 point (f) of the Financial Regulation. The award of a direct grant is duly justified as the beneficiaries identified by the PGI are the only partners of the Africa CDC that have the necessary technical competence and degree of specialisation. The beneficiaries will receive an invitation to submit a proposal either as a consortium or individually.

The proposed action will contribute to strengthening preparedness to respond to cross-border health threats in the Union through improvement, among others, of surveillance, early detection and warning systems including at global level in synergy with EDCTP3<sup>56</sup> and the Team Europe Initiative with Africa on Health security using a One health approach.

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

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

In the field of sequencing, the PGI is working closely with APHF and ASLM and its Member States and partners to address four key elements of sustainable public health pathogen genomics in Africa. These include establishing a continental capacity and network of Pathogen Genomics and Bioinformatics, developing a continental Data Management and Exchange Platform, workforce development in genomics and bioinformatics and engagement and prioritization of high-impact genomic-use to enhance surveillance for the continent.

This action aims at supporting:

- a) development of a data management platform and support African Union member states to build local data analytics capacity for rapid outbreak response;
- b) scaling up sequencing-based surveillance whereby Next Generation Sequencing (NGS) combined with various bioinformatics data analysis is used to track sources of outbreaks and detect outbreak clusters;
- c) strengthen the network capacity to ensure detection of new SARS-CoV-2 variants and systematically implement AMR surveillance and deploy NGS for the control and elimination of other cross border health threats.

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<sup>55</sup> Taking into account the HERA priority list of cross border health threats.

<sup>56</sup> Work programme 2022 Global Health EDCTP3.



## EXPECTED RESULTS AND IMPACT

This activity in coordination and synergy with current initiatives at EU level will increase preparedness and response to cross-border health threats. In particular it will:

- a) strengthen the pathogen data analytics;
- b) strengthen the network to support outbreak detection;
- c) support AMR and other endemic diseases.

## BUDGET AND IMPLEMENTATION MODE

Topic/sub-topic	Estimated launch date	Budget
Direct grants – CP-g-23-22	Q1-Q2/2023	EUR 6 000 000
Procedure type	Implemented by	Entity
Direct grant in accordance with Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046	HERA/HaDEA	African Public Health Foundation (APHF), African Society of Laboratory Medicine (ASLM)

### **CP-g-23-05-01 Direct grants to nominated EU reference laboratories (II): support the set-up and operation of the EU reference laboratories for the Diagnostics of Human Pathogens Network (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU<sup>57</sup>)**

#### **Policy context**

Article 15 of the Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU provides that the Commission may 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.

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<sup>57</sup> 2020/0322 (COD), not yet published in the Official Journal.

Coordinated EU laboratory support strengthens preparedness, crisis management and outbreak response capacities in the Member States thereby representing an area with clear added value at EU level. Sustainable EU reference networks of Microbiology Laboratories also ensure an adequate response to biological threats, such as intentional release and bioterrorism, thus contributing to a high level of protection to biological agents and health security in Europe.

The Commission has supported Member States' laboratory cooperation, most recently through the EMERGE Joint Action<sup>58</sup> (Efficient response to highly dangerous and emerging pathogens). This JA ensures cooperation between 40 diagnostic laboratories specialised in highly-pathogenic agents, with health security relevance. Currently, this network is part of the SHARP Joint Action<sup>59</sup>, which works on improving preparedness and International Health Regulation (IHR) implementation, including laboratory preparedness.

Moreover, support for harmonisation of laboratory diagnostics, antimicrobial susceptibility and molecular profiling methods, multicentre method validation, technical capacity mapping, training of laboratory staff, and continuing quality assessment of laboratory testing are provided by the ECDC through coordination of EU-wide networks of microbiology laboratories.

The EU reference laboratories<sup>60</sup> shall be responsible for the coordination of 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) support in outbreak response, including monitoring, alert, investigation and capacities;
- g) training;
- h) assistance to implement the EU laboratory and surveillance strategies.

The network of EU reference laboratories shall be operated and coordinated by the ECDC, in cooperation with the WHO Reference Laboratories, and coordination with the laboratory network managed by HERA will be ensured.

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 best be carried out by the established EU reference laboratories, which solely have the required competence and responsibility to implement the action.

This action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's

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<sup>58</sup> [EMERGE - EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level \(rki.eu\)](#).

<sup>59</sup> [SHARP Joint Action \(sharpja.eu\)](#).

<sup>60</sup> <https://www.ecdc.europa.eu/en/publications-data/core-functions-microbiology-reference-laboratories-communicable-diseases>.

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**

Taking into account the outcomes of the preparatory work carried out in action CP-p-23-05-02 - EU reference laboratories I, the EU reference laboratories will be designated based on priority topics and budget availability. The main tasks of the EU reference laboratories are defined as follows:

- a) to set up and coordinate a network of national reference laboratories for the disease(s) / health issue(s) it has been designated for. This must take into account any previous or existing national reference laboratory network, including those operated by ECDC, to support a smooth transfer and/or continuation of any relevant activities and information;
- b) to support the network of national reference laboratories by establishing and maintaining EU reference laboratory function(s) for the disease(s) / health issue(s) it has been designated for. This should be done in collaboration with ECDC;
- c) to participate in coordination activities organised by the ECDC and/or the WHO Reference Laboratories.

#### **EXPECTED RESULTS AND IMPACT**

The expected results are the following:

- a) establishment of one or more EU reference laboratories for disease(s) / health issue(s) that are of priority at EU level;
- b) implementation of EU reference laboratory support capacities for national public health reference laboratories within these priority areas.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – CP-g-23-05-01	Q3-Q4/2023	EUR 7 800 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to the EU reference laboratories in accordance with Article 195, first paragraph, point	HaDEA	National public health laboratories with demonstrated expertise in the relevant disease(s) /

(d) of Regulation (EU, Euratom) 2018/1046		health issue(s)
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## 2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

### 2.1 HEALTH PROMOTION AND PREVENTION OF NON-COMMUNICABLE DISEASES (NCDs)

#### **DP-g-23-31-01 Direct grants to Member States' authorities: 'Healthier Together' EU NCD initiative<sup>61</sup> – chronic respiratory diseases (CRDs)**

##### **POLICY CONTEXT**

Chronic respiratory diseases (CRDs), which are diseases of the airways and other structures of the lung, are one of the main sources of premature mortality and morbidity in the Union. Some of the most common are chronic obstructive pulmonary disease (COPD), asthma, occupational lung diseases and pulmonary hypertension. In addition, the interstitial lung disease, that covers a large group of chronic lung diseases that cause scarring (fibrosis) of the lungs and post-COVID pulmonary fibrosis, need attention as well.

CRDs account for 8% of all premature deaths in the Union and 3% of all deaths are caused by COPD<sup>62</sup>. There are inequalities across the Union as well as within Member States as regards chronic respiratory diseases. A larger proportion of men (8.1%) than of women (6.9%) die because of respiratory diseases in the Union (data from 2016).

Many CRDs are treatable and to a large extent, preventable. Beside genetics, tobacco smoking, chronic exposure to air pollutants and airway allergens, occupational and environmental chemicals and dust, and frequent lower respiratory infections during childhood are the major causes of CRDs<sup>63</sup>. Second-hand exposure to tobacco smoke is a risk factor for CRDs, especially in the case of children and adolescents since they have a bigger risk than adults to be adversely affected by regular second-hand exposure to tobacco smoke.

The 'Healthier Together' EU NCD Initiative has identified possible priority areas for action on CRDs that include the prevention of the onset and progress, in particular of COPD, relevant vaccination programmes, early detection of CRDs and improving CRDs self-management support.

The Commission has carried out a call for best practices in the EU best practice portal<sup>64</sup> in 2022. The resulting best practices have been presented to the Member States on 8 and 9 September in view of their possible uptake and transfer at the national level. This repository includes best practices on NCDs, including on CRDs and their prevention.

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

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<sup>61</sup> [EU Non-communicable diseases \(NCDs\) initiative: Guidance document \(europa.eu\).](https://europa.eu/european-council/en/eu-non-communicable-diseases-ncds-initiative-guidance-document)

<sup>62</sup> OECD/European Union (2020), Health at a Glance: Europe 2022: State of Health in the EU Cycle, OECD Publishing, Paris, <https://doi.org/10.1787/82129230-en>.

<sup>63</sup> [Chronic respiratory diseases \(who.int\).](https://www.who.int/news-room/fact-sheets/detail/chronic-respiratory-diseases)

<sup>64</sup> [pb-portal \(europa.eu\).](https://europa.eu/european-council/en/eu-best-practice-portal)

The joint action will support the policy objective of reducing the burden of CRDs 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 (i), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this joint action is to reduce the burden of CRDs and their risk factors, both at personal and population level, and to support the Member States in their efforts to meet the Sustainable Development Goals<sup>65</sup>, in particular Goal 3, Target 3.4<sup>66</sup>, as well as the NCDs targets of the WHO<sup>67</sup>.

The activities will include the implementation of comprehensive public health policies, transferring of best practices and innovative approaches, development of guidelines, and launching of actions expected to have a significant public health impact. It will include possible areas of cooperation and synergy with the Zero Pollution Action Plan<sup>68</sup>, the EU’s Chemicals Strategy for Sustainability<sup>69</sup> and the Europe’s Beating Cancer Plan.

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

The joint action will take into account results of relevant Horizon 2020<sup>70</sup> projects, as well as of relevant Horizon Europe projects and it will be complemented by the action “DP-g-23-31-02 Call for proposals to support stakeholders on prevention of NCDs in the area of chronic respiratory diseases (CRDs)”.

#### **EXPECTED RESULTS AND IMPACT**

The joint action will support the definition and roll-out of best practices for implementation through population-level disease prevention and health promotion interventions and other actions expected to reduce the burden of CRDs in the Member States.

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

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<sup>65</sup> THE [17 GOALS | Sustainable Development \(un.org\)](https://www.un.org/sustainabledevelopment/).

<sup>66</sup> Sustainable development goals (SDGs) : Goal 3. Target 3.4 : by 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and wellbeing.

<sup>67</sup> <https://www.who.int/>.

<sup>68</sup> [Zero pollution action plan \(europa.eu\)](https://ec.europa.eu/euro-observatory/en/zero-pollution-action-plan).

<sup>69</sup> [Chemicals strategy \(europa.eu\)](https://ec.europa.eu/chemicals/strategy).

<sup>70</sup> [CORDIS | European Commission \(europa.eu\)](https://cordis.europa.eu/).

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants - DP-g-23-31-01	Q3/2023	EUR 4 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

## **DP-g-23-32-01 Direct grants to Member States’ authorities: ‘Healthier Together’ EU NCD initiative – Mental health**

### **POLICY CONTEXT**

Mental ill-health<sup>71</sup> is one of the main sources of morbidity in the Union, at a very high cost, also to social protection systems and the economy. Population mental health has been significantly affected by the pandemic and the Russian war of aggression against Ukraine, especially for vulnerable groups, such as refugees and displaced people from Ukraine.

Before the onset of the COVID-19 pandemic, mental health problems affected about 84 million people in the EU, amounting to one in every six citizens, at an estimated cost of over EUR 600 billion (more than 4% of GDP). There were also indications of increased risk of mental health problems among young people aged 12–24 years, especially among those living with chronic health conditions, living in rural areas, and those not in education, training or employment. The COVID-19 pandemic exacerbated these already sobering data. Around 10 to 20% of school children in Europe are experiencing mental health issues during their school years, and with half of them developing problems before the age of 14, in particular anxiety and depression. This is a major problem which negatively affects educational outcomes. If schools alone cannot solve these problems, they can help address well-being and mental health issues in cooperation with local community and external professionals and agencies<sup>72</sup>. A significant decrease in mental well-being and an increase in negative feelings, such as tension/anxiety, loneliness, and feeling downhearted and depressed, was recorded across all age groups since the summer of 2020, reaching its lowest level across all age groups in spring 2021. Population groups whose mental health has been particularly affected by the pandemic include young people, people with less secure employment, and people with less education or a lower income. Adversity is an established risk factor for mental health and behavioural problems. Examples of such adversities include poverty, unemployment, financial instability, a low educational level, violence, homelessness, and social isolation.

It is vital to not only address the needs of people with defined mental disorders but also to protect and promote the mental health of all people, and recognise the intrinsic value of positive mental health. The ‘Healthier Together’ EU NCD Initiative aims to promote mental health and prevent and address at the population-level mental health problems and mental disorders, and to set up ways to support people living with mental disorders. The initiative identifies possible priority areas for action that include supporting favourable conditions for mental health and increasing resilience, implementing Mental Health in All Policies<sup>73</sup>,

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<sup>71</sup> The broad terms “mental ill-health”, “mental illness” and “mental health problems” are used interchangeably and refer to mental disorders but also include psychological distress, i.e. symptoms or conditions that do not reach the clinical threshold of a diagnosis within the classification systems but which can account for significant suffering and hardship, and can be enduring and disabling. Mental disorders are defined as those reaching the clinical threshold of a diagnosis according to psychiatric classifications systems including disorders such as depression, anxiety, bipolar disorder and schizophrenia. (OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris. [https://doi.org/10.1787/health\\_glance\\_eur-2018-en](https://doi.org/10.1787/health_glance_eur-2018-en)).

<sup>72</sup> European Commission, Directorate-General for Education, Youth, Sport and Culture, Simões, C., Caravita, S., Cefai, C., A systemic, whole-school approach to mental health and well-being in schools in the EU: analytical report, 2021, <https://data.europa.eu/doi/10.2766/50546>.

<sup>73</sup> [Mental health in all policies \(europa.eu\)](https://data.europa.eu/doi/10.2766/50546).



promoting mental health and preventing mental disorders through sport and physical activity<sup>74</sup> and improving timely and equitable access to high quality services, protecting human rights, enhancing social inclusion and tackling stigma associated with mental health problems.

Among children and adolescents, physical activity provides benefits for cognitive development, motor skills, self-esteem, social integration, musculoskeletal health, academic achievement and overall well-being. The award of a direct grant as referred to in Article 13 (5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by the Member States' authorities that have the required competences and responsibilities to implement the Union policies at national level.

The joint action will support the policy objective of reducing the burden of mental health problems 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), (b) and (i), of Regulation (EU) 2021/522.

### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this joint action is to reduce the burden of mental health problems and improve mental health, as well as addressing mental health problems and disorders, both at personal and population level, and to support Member States in their efforts.

The activities will include implementation of comprehensive public health policies and policy mechanisms, the Mental Health in All Policies approach, transferring of best practices and innovative approaches, development of guidelines, and launching of actions expected to have a significant public health impact and contribute to suicide prevention, including in different settings, such as educational settings<sup>75</sup>. Targeted actions will support particularly vulnerable groups such as migrants, refugees, Roma people and persons displaced from Ukraine.

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

The joint action will take into account results of relevant Horizon 2020<sup>76</sup> projects as well as Horizon Europe projects, and it will be complemented by the action "DP-g-23-32-02 Call for proposals on prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine".

### **EXPECTED RESULTS AND IMPACT**

This joint action will support the efforts of the Member States to reduce the burden of NCDs (approximately 80% of the disease burden in Europe), in particular that related to mental health problems, and to reach the Sustainable Development Goal 3, in particular target 3.4.

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

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<sup>74</sup> WHO guidelines on physical activity and sedentary behaviour. Geneva: World Health Organization; 2020.

<sup>75</sup> In line with Pathways to School Success initiative [Pathways to School Success | European Education Area \(europa.eu\)](#); [EUR-Lex - 52022DC0316 - EN - EUR-Lex \(europa.eu\)](#).

<sup>76</sup> [CORDIS | European Commission \(europa.eu\)](#).

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – DP-g-23-32-01	Q3/2023	EUR 6 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

## **DP-g-23-33-01 Direct grants to Member States’ authorities: ‘Healthier Together’ EU NCD initiative – Dementia and other neurological disorders**

### **POLICY CONTEXT**

Neurological disorders (including dementia) are among the main sources of morbidity in the Union.

Neurological disorders are conditions characterised as being in or associated with the central or peripheral nervous system. Major non-communicable neurological disorders are Alzheimer’s disease, which is the main cause of dementia, and other forms of dementia, cerebrovascular diseases including stroke, Parkinson’s disease, multiple sclerosis, epilepsy, various headache disorders among which migraine, and traumatic brain injuries. In general, specific rare diseases are addressed in other Union programmes and actions<sup>77</sup>. As the prevalence of the major disabling neurological disorders steeply increases with age, there will be an increasing demand for prevention, diagnosis, treatment, and rehabilitation and support services for neurological disorders in the coming years in all countries with ageing populations. The ‘Healthier Together’ EU NCD Initiative identifies possible priority areas for action on neurological disorders that include for example, health promotion, disease prevention and early detection of neurological diseases, developing and implementing national plans for stroke, tackling stigma associated with dementia, and implementing person-centred integrated care models.

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

The joint action will support the policy objective of reducing the burden of dementia and other neurological disorders, 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 (i), of Regulation (EU) 2021/522.

### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this joint action is to reduce the burden of dementia and other neurological disorders, both at individual and population level, and to support the Member States in their efforts.

The activities will include implementation of comprehensive public health policies and policy mechanisms, transferring of best practices and innovative approaches, development of guidelines and launching of actions expected to have a significant public health impact.

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

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<sup>77</sup> ERN-RND | European Reference Network on Rare Neurological Diseases – for rare or low prevalence complex diseases.

The joint action will take into account results of relevant Horizon 2020 projects<sup>78</sup>, as well as relevant Horizon Europe projects, and it will be complemented by the action “DP-g-23-33-02 Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders”.

#### EXPECTED RESULTS AND IMPACT

Support to the efforts of the Member States to reduce the burden of NCDs (approximately 80% of the disease burden in Europe), in particular that related to dementia and other neurological disorders, and to reach the Sustainable Development Goal 3, in particular target 3.4.

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

#### INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - DP-g-23-33-01	Q3/2023	EUR 4 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

### DP-g-23-31-02 Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases

#### POLICY CONTEXT

Chronic respiratory diseases (CRDs), which are diseases of the airways and other structures of the lung, are one of the main sources of mortality and morbidity in the Union. Some of the most common are chronic obstructive pulmonary disease (COPD), asthma, occupational lung diseases and pulmonary hypertension. In addition, the interstitial lung disease, that covers a large group of chronic lung diseases that cause scarring (fibrosis) of the lungs and post-COVID Pulmonary Fibrosis, needs attention as well.

<sup>78</sup> [CORDIS | European Commission \(europa.eu\)](https://cordis.europa.eu/), e.g. IMI2 project RADAR AD (<https://www.imi.europa.eu/projects-results/project-factsheets/radar-ad>).

Respiratory diseases account for 8% of all deaths in the Union and 3% of all deaths are caused by COPD<sup>79</sup>. Mortality rates because of respiratory diseases vary not only across the Member States, but also within countries. A larger proportion of men (8.1%) than of women (6.9%) die because of respiratory diseases in the Union (2016). About 5.7% of the adult EU population were reported to have asthma and 4.7% another medically confirmed lower respiratory disease, including COPD<sup>80</sup>.

Many CRDs, including asthma and COPD, are treatable and to a large extent, preventable. Beside genetics, tobacco smoking, chronic exposure to air pollutants and airway allergens, occupational and environmental chemicals and dust, and frequent lower respiratory infections during childhood are the major causes of CRDs<sup>81</sup>. Second-hand exposure to tobacco smoke is a risk factor for CRDs, especially in the case of children and adolescents, as they are at greater risk than adults of being adversely affected by regular second-hand exposure to tobacco smoke within their home environments.

This action supports the policy objective of reducing the burden of CRDs 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 (i), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this action is to complement the implementation of the joint action “DP-g-23-31-01 ‘Healthier Together’ EU NCD Initiative – Chronic respiratory diseases” led by the Member States, thus helping to reduce the burden of CRDs in the Union, both at personal and population level, targeting or addressing the related risk factors and their determinants, as necessary.

The activities will cover the prevention and management of CRDs and will complement the joint action. Activities will include implementing projects involving civil society organisations to support the Member States' authorities in the implementation of comprehensive public health policies, the development and transfer of best practices, the development of public health guidelines, the preparation and roll-out of innovative approaches, projects supporting patient pathways and the launching of projects expected to have a significant public health impact and which benefit citizens directly. These may include projects to support the Member States in meeting the objectives of the Zero Pollution Action Plan<sup>82</sup>, the Chemicals Strategy for Sustainability<sup>83</sup> and of the Europe's Beating Cancer Plan.

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

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<sup>79</sup> OECD/European Union (2020), Health at a Glance: Europe 2022: State of Health in the EU Cycle, OECD Publishing, Paris, <https://doi.org/10.1787/82129230-en>.

<sup>80</sup> [Respiratory diseases statistics - Statistics Explained \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&code=sdg_3_6_2).

<sup>81</sup> [Chronic respiratory diseases \(who.int\)](https://www.who.int/news-room/fact-sheets/detail/chronic-respiratory-diseases).

<sup>82</sup> [https://environment.ec.europa.eu/strategy/zero-pollution-action-plan\\_en](https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en).

<sup>83</sup> [Chemicals strategy \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&code=sdg_3_6_2).

## EXPECTED RESULTS AND IMPACT

The action will implement projects on health promotion and disease prevention, and is expected to support the Member States' efforts to reduce the burden of NCDs (approximately 80% of the disease burden in Europe), in particular that related to CRDs, and to reach the Sustainable Development Goal 3, in particular target 3.4.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as for the development of public health guidelines, patient pathways, and support for the preparation and roll-out of new policy approaches, participation in the pilot testing of innovative practices, development of support actions such as training and improving health awareness and health literacy.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals – DP-g-23-31-02	Q2-Q3/2023	EUR 1 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals (action grants)	HaDEA	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, foundations, NGOs and similar entities)

## **DP-g-23-32-02 Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine**

### POLICY CONTEXT

Mental ill-health is one of the main sources of morbidity in the Union, at a very high cost, also to social protection systems and the economy. Population mental health has been significantly affected by the pandemic and the Russian war of aggression against Ukraine, especially vulnerable groups, including refugees and displaced people from Ukraine.

Before the onset of the COVID-19 pandemic, mental health problems affected about 84 million people in the Union, amounting to one in every six citizens, at an estimated cost to health systems and social security programmes of over EUR 600 billion (more than 4% of

GDP)<sup>84,85</sup>. There were also indications of increased risk of mental health problems among young people aged 12–24 years, especially among those living with chronic health conditions, living in rural areas, and those not in education, training or employment<sup>86</sup>. The COVID-19 pandemic exacerbated these already sobering data. A significant decrease in mental well-being and an increase in negative feelings, such as tension/anxiety, loneliness, and feeling downhearted and depressed, was recorded across all age groups since the summer of 2020, with mental well-being dropping significantly across all age groups in spring 2021<sup>87</sup>. Increased sleep dysfunction has also been observed among general populations<sup>88</sup>. Population groups whose mental health has been particularly affected by the pandemic include young people, people with less secure employment, and people with less education or a lower income<sup>89</sup>. Adversity is an established risk factor for mental health and behavioural problems<sup>90</sup>. Examples of such adversities include poverty, unemployment, financial instability, a low educational level, violence, homelessness, and social isolation.

Displaced and newcomer children often have educational and psychological challenges linked to their recent arrival in the country. They may have interrupted formal education, and may have arrived without their parents, family and established social networks. In addition, they may be suffering from traumatic experiences in their countries of origin and during travel, and may also face difficult conditions in reception centres. This can result in psycho-social and educational difficulties, with different degrees of severity requiring different levels of support<sup>91</sup>. The ‘Healthier Together’ EU NCD Initiative aims to promote mental health and prevent and address mental health problems and mental disorders and support people living with mental disorders. The initiative identifies possible priority areas for action that include supporting favourable conditions for mental health and increasing resilience, implementing Mental Health in All Policies<sup>92</sup>, promoting mental health and preventing mental disorders and improving timely and equitable access to high quality services, protecting rights, enhancing social inclusion and tackling stigma associated with mental health problems.

This action supports the policy objective of promoting mental health and preventing and addressing mental health problems and disorders and implements the EU4Health

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<sup>84</sup> OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris. [https://doi.org/10.1787/health\\_glance\\_eur-2018-en](https://doi.org/10.1787/health_glance_eur-2018-en).

<sup>85</sup> The most common mental disorder across EU countries is anxiety disorder, followed by depressive disorder, drug and alcohol use disorder, and several severe mental illness, such as bipolar disorder and schizophrenia, see [https://ec.europa.eu/health/sites/health/files/state/docs/2018\\_healthatglance\\_rep\\_en.pdf](https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf).

<sup>86</sup> [Challenges and prospects in the EU: Quality of life and public services \(europa.eu\)](#).

<sup>87</sup> [Living, working and COVID-19 \(Update April 2021\): Mental health and trust decline across EU as pandemic enters another year \(europa.eu\)](#).

<sup>88</sup> Bhat S, Chokroverty S. Sleep disorders and COVID-19. *Sleep Med.* 2022 Mar;91:253-261. doi: 10.1016/j.sleep.2021.07.021. Epub 2021 Jul 18. PMID: 34391672; PMCID: PMC8286239.

<sup>89</sup> OECD (2021), Health at a Glance 2021: OECD Indicators, OECD Publishing, Paris, <https://doi.org/10.1787/ae3016b9-en>.

<sup>90</sup> [Mental health preparedness and response during for the COVID-19 pandemic \(who.int\)](#).

<sup>91</sup> [Commission presents key principles and practices for supporting the inclusion of displaced children from Ukraine in school education | European Education Area \(europa.eu\)](#); [Register of Commission Documents - SWD\(2022\)185 \(europa.eu\)](#).

<sup>92</sup> [Mental health in all policies \(europa.eu\)](#).

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 (i), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this action is to complement the implementation of the joint action “DP-g-23-32-01 ‘Healthier Together’ EU NCD Initiative – Mental Health” led by the Member States, thus helping to promote mental health, and to reduce the burden of mental health problems in the Union, both at individual and population level, targeting or addressing the related risk factors and their determinants, as necessary.

The activities will cover the promotion of mental health and prevention and management of mental health problems, supporting in particular vulnerable population groups (migrants, refugees, Roma people and displaced people from Ukraine). The activities will run in parallel to the joint action and will include the implementation of projects involving civil society organisations to support the Member States' authorities in implementing comprehensive public health policies, the development and transfer of best practices, the development of public health guidelines, the preparation and roll-out of innovative approaches and projects supporting patient pathways, and launching of targeted projects to support vulnerable groups including migrants, refugees, Roma people and displaced persons from Ukraine.

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

#### **EXPECTED RESULTS AND IMPACT**

The action will implement projects on health promotion and disease prevention, taking into account relevant results of Horizon 2020<sup>93</sup> and Horizon Europe projects, and is expected to support the Member States' efforts to reduce the burden of NCDs (approximately 80% of the disease burden in Europe), in particular that related to mental health problems, and to reach the Sustainable Development Goal 3, in particular target 3.4.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as for the development of public health guidelines, supporting patient pathways, and support for the preparation and roll-out of new policy approaches, participation in the pilot testing of innovative practices, development of support actions such as training and improving health awareness and health literacy.

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<sup>93</sup> [CORDIS | European Commission \(europa.eu\)](https://cordis.europa.eu/), e.g. RefugeesWellSchool (<https://cordis.europa.eu/project/id/754849>).



## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – DP-g-23-32-02	Q2-Q3/2023	EUR 2 360 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, foundations, NGOs and similar entities)

### **DP-g-23-33-02 Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders**

#### **POLICY CONTEXT**

Neurological disorders (including dementia) are among the main sources of morbidity in the Union.

Neurological disorders are conditions characterised as being in or associated with the central or peripheral nervous system. Major non-communicable neurological disorders are Alzheimer’s disease, which is the main cause of dementia, and other forms of dementia, cerebrovascular diseases including stroke, Parkinson’s disease, multiple sclerosis, epilepsy, various headache disorders among which migraine, and traumatic brain injuries. Many more – both communicable and non-communicable – neurological disorders exist, often also with a substantial disease burden and premature mortality. These latter diseases are addressed in Union programmes and actions on rare diseases. Neurological disorders are the leading cause of disease burden in terms of Disability-Adjusted Life Years (DALYs) and second<sup>82</sup> leading cause of deaths (2016). The four largest contributors of neurological DALYs in 2016 were stroke (42%), migraine (16%), Alzheimer’s disease and other dementias (10%), and meningitis (8%), the latter not being an NCD. As the prevalence of the major disabling neurological disorders steeply increases with age, there will be an increasing demand for treatment, rehabilitation and support services for neurological disorders in the coming years in all countries with ageing populations.

The ‘Healthier Together’ EU NCD Initiative has identified possible priority areas for action on neurological disorders, that include implementing national plans for stroke, changing attitudes towards dementia, and tackling stigma associated with dementia, prevention and early detection of neurological diseases, in particular Alzheimer’s disease and dementia, and implementing person-centred integrated care models.

This action supports the policy objective of reducing the burden of dementia and other neurological disorders, 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 (i), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this action is to complement the implementation of the joint action “DP-g-23-33-01 ‘Healthier Together’ EU NCD Initiative – Dementia and neurological disorders” led by the Member States, thus helping to reduce the burden of dementia and other neurological disorders in the Union, both at personal and population level, targeting or addressing the related risk factors and their determinants, as necessary.

The activities will cover the prevention and care of dementia and other neurological disorders, taking into account relevant results of Horizon 2020 projects<sup>94</sup>, and of relevant Horizon Europe projects, and will run in parallel to the joint action. Activities will include the implementation of projects involving civil society organisations to support the Member States’ authorities in implementing comprehensive public health policies, the development and transfer of best practices, the development of public health guidelines, the preparation and roll-out of innovative approaches and projects supporting patient pathway, and launching of projects, such as on training, health awareness and health literacy, that are expected to have a significant public health impact.

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

#### **EXPECTED RESULTS AND IMPACT**

The action will implement activities on health promotion and disease prevention, and is expected to support the Member States’ efforts to reduce the burden of non-communicable diseases (approximately 80% of the disease burden in Europe), in particular that related to dementia and other neurological disorders, and to reach the Sustainable Development Goal 3, in particular target 3.4.

The expected results will include initiatives to complement the Member States’ efforts in the design, planning and implementation of best practices, such as for the development of public health guidelines, supporting patient pathways, and support for the preparation and roll-out of new policy approaches, participation in the pilot testing of innovative practices, development of support actions such as training and improving health awareness and health literacy.

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<sup>94</sup> [CORDIS | European Commission \(europa.eu\)](https://www.imi.europa.eu/projects-results/project-factsheets/radar-ad), such as the IMI2 project RADAR AD (<https://www.imi.europa.eu/projects-results/project-factsheets/radar-ad>).

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals – DP-g-23-33-02	Q2-Q3/2023	EUR 1 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals (action grants)	HaDEA	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, foundations, NGOs and similar entities)

**DP-g-23-34 Call for proposals for operating grants to NGOs: 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 EU, national and local levels. In the field of health, and specially public health, they provide services directly to patients and individuals being in some cases in the first line of action also during emergencies. NGOs are also essential in bridging the gap between institutions and patients and facilitating communication at national and EU level. These organisations are not-for-profit and therefore necessarily rely on funding from different sources, for instance private donations, national or international contributions.

The Commission considers 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.

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

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

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

The operating grants linked to a specified time-frame and specific outputs or results are intended to provide support to health NGOs that pursue one or more of the general objectives (Article 3 (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 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 2023 for activities including awareness raising on various health aspects, communication and dissemination, capacity building and training, expert collaboration and networking.

#### **EXPECTED RESULTS AND IMPACT**

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

The beneficiaries are expected to further demonstrate in their proposals the EU 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 EU capacity-building and training activities to reduce the impact of risk factors for non-communicable diseases; new approaches to promote healthy and sustainable diets; expert guidance and peer-to-peer connections; and collaborate in shared areas of activity.

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

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

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Operating grants – DP-g-23-34	Q1/2023	EUR 9 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals	HaDEA	NGOs active in the public health area

### 3. CANCER (CR)

#### 3.1 STRATEGIC AGENDA FOR MEDICAL IONISING RADIATION APPLICATIONS (SAMIRA)

##### **CR-g-23-44-01 Call for proposals to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA<sup>95</sup>) – organisation of clinical audit campaigns as a tool to improve the quality and safety of medical applications of ionising radiation**

###### POLICY CONTEXT

A variety of nuclear and radiation technologies play a key role in the fight against cancer. Mammography, computed tomography and other forms of radiological imaging are indispensable technologies for all stages of cancer management. Radiotherapy is among the most effective, efficient and widely used cancer treatments available to patients and physicians. Nuclear medicine (e.g. radiopharmaceutical treatments and radiodiagnostics) is routinely used for cancer diagnosis and follow-up, and increasingly available for cancer treatment.

The Euratom Treaty<sup>96</sup> defines a key EU competence for health and safety with respect to ionising radiation, and the Union has established an ambitious legislative framework for protecting patients, volunteers in medical research and medical staff from the undesirable effects of this radiation. The Euratom Basic Safety Standards (BSS) Directive<sup>97</sup> introduces requirements, such as those for justification of individual patient exposures, quality assurance and clinical audit, which are applicable to all kinds of medical practice involving ionising radiation.

In February 2021, the Commission adopted the SAMIRA action plan, which sets out a series of actions to advance the quality and safety of medical procedures involving ionising radiation, with the aim of bringing tangible benefits to patients by ensuring that these procedures are used strictly in line with clinical needs and with the highest standards of quality and safety. These actions provide an important contribution to the Europe's Beating Cancer Plan objectives of ensuring sustainable cancer prevention, supporting the early detection of cancer and ensuring access to high standards of diagnosis and treatment. The SAMIRA action plan also contributes to support the implementation of the BSS Directive in particularly challenging areas, for example those requiring changes in the organisation and resource allocation in healthcare, such as clinical audit. Past studies and more recent work from the Commission showed that the clinical audit practice in the Member States differs considerably.

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<sup>95</sup> [SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications \(europa.eu\)](#).

<sup>96</sup> The Euratom Research and Training Programme covers nuclear research and innovation - [Euratom Research and Training Programme \(europa.eu\)](#).

<sup>97</sup> 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 Directive 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ, L 013 17.1.2014, p.1).

To improve the situation, in 2019, the Commission launched the QuADRANT project whose objective was to promote constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through the implementation of clinical audit. The project resulted in a report identifying good practices in Member States and available guidance and resources for clinical audits, at national, European and international level and providing further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems. Additionally, the EU-JUST-CT project, which started in April 2021 and runs until March 2024, is conducting pilot audits of justification of computed tomography procedures in several Member States following a common methodology.

The Steering Group on Quality and Safety (SGQS) created by the Commission under the SAMIRA initiative identified this topic as a priority area of work, and a working group has been created to define further actions for improving the implementation of clinical audit in Member States' health systems.

This action will contribute to the implementation of the Europe's Beating Cancer Plan and supports the policy objective of ensuring access to high standards in cancer diagnosis and treatment, 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 objective of this action is to pilot clinical audit campaigns in Member States in diagnostic and interventional radiology, radiotherapy and nuclear medicine by identifying and bringing together relevant actors and resources. It should take into account the specificities of the national health systems. It will include coordination, planning, recruiting, training, auditing and reporting activities. It should build on the results of the QuADRANT and the EU-JUST-CT project.

Up to four proposals of different sizes will be accepted, ranging from organising pilot audits in a single (large) department or hospital, a hospital trust, a region or a single Member State to coordinated audits in several Member States and should be implemented in coordination with the appropriate health authorities. A priority will be given to proposals covering several types of medical practice in several Member States and also to different practices within different regions of a Member State. Proposals should include considerations and activities to scale up pilot outcomes into the broader health system practice of Member State(s).

In particular, the clinical audit action should seek to improve justification of radiological imaging, in line with the 2015 Council conclusions on this topic<sup>98</sup>, and the implementation of the optimisation principle.

The action will be implemented in close cooperation with other SAMIRA activities on quality and safety of medical applications of ionising radiation and include a reporting on the pilots carried out in Member States to the SGQS.

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<sup>98</sup> Council conclusions on the justification of medical imaging involving exposure to ionising radiation, adopted by the Council at its 3433rd meeting held on 3 December 2015.

## EXPECTED RESULTS AND IMPACT

The action will contribute to a better implementation of the BSS Directive's requirement with regard to clinical audit taking into account the differing challenges across Member States. It can serve as a reference action to establish a permanent clinical audit mechanism in some Member States.

It will improve the overall quality and safety of radiological medical procedures in order to bring their full benefits to patients. It will contribute to the development of the professional skills of the auditors and of the audited professionals and foster inter-disciplinary and multi-professional relationships. It should contribute to the development of leadership in this area.

This action could also strengthen structures involved in hospital accreditation or individuals involved in professional healthcare certification schemes.

The pilot outcomes should be relevant to health systems as a whole and be designed in a way that their outcomes can be scaled up into the broader health system practice of the Member State(s).

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals CR-g-23-44-01	Q2-Q3/2023	EUR 1 500 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open calls for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks, Member States' authorities and established networks in the field of public health



## **CR-g-23-44-03 Direct grants to Member States' authorities: to support implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – Preparatory activities for a future joint action on quality and safety of medical applications of ionising radiation under the SAMIRA initiative**

### **POLICY CONTEXT**

The Commission is committed to ensuring that citizens receive the best possible protection from the undesirable effects of ionising radiation, while fully benefiting from the advantages it offers in battling cancer and other diseases. Notwithstanding recent developments in the European regulatory framework, there remains room for improvement of the quality and safety of medical radiation applications.

In February 2021, the Commission adopted the SAMIRA action plan, an important contribution to Europe's Beating Cancer Plan, with the aim of supporting the implementation of high standards for quality and safety of medical applications of ionising radiation into Member States' health systems. The SGQS, created under SAMIRA and composed of representatives from the health and the radiation protection authorities, provides strategic guidance and prioritisation of activities and advises the Commission on the use of the available EU instruments and programmes to implement the SAMIRA quality and safety actions. The SGQS draws conclusions from relevant activities and projects, and advises the Commission on concrete actions to improve the uptake of best practices, recommendations and guidelines, as well as research and innovation results.

The topical areas of the SGQS work programme are the following:

- a) data collection for quality & safety related actions;
- b) development of high-quality evidence, clinical guidelines, standards and practical tools for quality and safety (including the implementation of clinical audits in radiology, radiotherapy and nuclear medicine);
- c) coordinated implementation of the relevant Euratom<sup>99</sup> and Union law (e.g. for radiation protection, medical devices and radiopharmaceuticals);
- d) actions to support adequate workforce availability, education and training;
- e) actions to support EU patients' access to modern equipment and procedures used in radiology, radiotherapy and nuclear medicine;
- f) identification and sharing of good practices in radiology, radiotherapy and nuclear medicine; and
- g) other areas where the SGQS considers that specific actions are needed.

A series of SAMIRA-related projects and studies have already been launched (EU-JUST-CT, SIMPLERAD, EU-REST, i-Violin, Equipment study, Incidents study), other studies' results

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<sup>99</sup> The Euratom Research and Training Programme covers nuclear research and innovation – [Euratom Research and Training Programme \(europa.eu\)](https://euratom.europa.eu).

are available (QuADRANT, MEDIRAD), and the need for a sustainable framework for the implementation of those studies' findings in Member States has emerged. This framework could take the form of a joint action.

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

This joint action supports the implementation 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 defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objective of this preparatory activity is to explore the utility of and pave the way for a future joint action in the area of quality and safety of medical applications of ionising radiation. This preparatory activity will include:

- a) the mapping of the relevant actors in Member States in the quality and safety area and of their field of expertise;
- b) networking activities among those actors;
- c) the detailed definition of the objectives, scope and activities of the future joint action, based on the SGQS work programme and its outputs;
- d) communication activities, in order to promote the future initiative and to mobilise the actors identified above.

This preparatory joint action will be implemented in close cooperation with other SAMIRA activities on the quality and safety of medical applications of ionising radiation and will include regular reporting to the SGQS.

#### **EXPECTED RESULTS AND IMPACT**

This preparatory joint action will help promote the planned joint action on Quality and Safety (CR-g-23-44-03) and generate support to it. It will start establishing a network of actors that could then interact in the long-term and be involved in the future joint action. In the end, it will ensure a better implementation of the results of SAMIRA studies and projects in the Member States and improve the quality and safety of medical applications of ionising radiation.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – CR-g-23-44-03	Q2-Q3/2023	EUR 1 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>

Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities
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### 3.2 MENTAL HEALTH AND CANCER

#### **CR-g-23-19.01/02 Call for proposals: action grants on mental health challenges for cancer patients and survivors**

##### **POLICY CONTEXT**

Every year around 2.7 million people living in the Union are diagnosed with cancer and the number of cancer survivors is growing every year with a continuous increase in 5-year survival rates for the most common cancer types in all countries. These improvements are driven by a number of factors, including effective prevention and screening programmes as well as advances in diagnostics and surgical techniques. The number of childhood cancer survivors is also expected to rise substantially in the years to come. While this is a reason for optimism, survivors, their families and carers can experience significant challenges. These challenges could often be avoided or mitigated by cooperation between health and social care systems, and as well as cooperation with employers. In this context, the focus should no longer be on ‘how long’ people live after diagnosis, but rather on ‘how well and how long’ they live. Europe’s Beating Cancer Plan and the EU Mission on Cancer aim not only to ensure that cancer patients survive their illness, but that they live long, fulfilling lives, free from discrimination and unfair obstacles. Cancer survivors face a number of common issues including unmet psychosocial needs, and issues related to rehabilitation, emotional distress, secondary cancers and tumour recurrence, including metastatic disease.

Up to 30% of children affected by cancer suffer severe long-term consequences. As the number of childhood cancer survivors continues to grow, comprehensive care, treatment and follow-up are essential to help young patients make a good recovery and enjoy an optimal quality of life. The new ‘Cancer Survivor Smart-Card’ will address the specificities of childhood cancer survivors, including psychological support. In addition, the EU Network of Youth Cancer Survivors<sup>100</sup> was launched in February 2022 to support the European Year of Youth. It will connect young cancer survivors and strengthen long-term follow-up in cancer care plans at national and regional level focusing also on mental health and psychosocial care.

There is a need to inform people about evidence-based actions they can take for themselves or their families to promote mental health and to reduce the risk of mental health problems. A European Code for Mental Health, based on the approach for the European Code against

<sup>100</sup> [Funding & tenders \(europa.eu\)](https://europea.eu) - EU Network of Youth Cancer Survivors (EU-CAYAS-NET); OAC Connects Us.

Cancer<sup>101</sup>, would help Member States and public health authorities in their efforts to promote mental health amongst their citizens.

This action will support the policy objective of reducing the burden of cancer and of mental health problems 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), (b) and (i), of Regulation (EU) 2021/522).

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

This action aims to address mental health challenges in cancer patients and survivors, and their carers<sup>102</sup> and families.

Sub-topic (a):

Activities will include:

- (i) systematic screening of the mental health status of cancer patients, their carers and families in order to identify persons at risk of developing mental health problems;
- (ii) development of methodologies that can support the identification of patients, their carers and families, with risk factors for mental health challenges, and the piloting and further testing of such methodologies to assess their impact and transferability at EU level;
- (iii) providing psychological and psychosocial support and targeted interventions for cancer patients, survivors, their carers and families in order to prevent long-term mental health consequences;
- (iv) developing guidance and recommendations for professionals to ensure mental health aspects throughout the entire patient care pathway;
- (v) provision of professional psychosocial support for children, adolescents and young adults with cancer.

Sub-topics (b):

Activities will include:

- (i) Development of a European Code for Mental Health which contains messages that are evidence-based, easy-to-understand and easy-to-implement for citizens about actions they can take for themselves or their families to reduce their risk of mental health problems<sup>103</sup>.

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<sup>101</sup> [European Code Against Cancer - International Agency for Research on Cancer \(IARC\). European Commission: 12 ways to reduce your cancer risk.](#)

<sup>102</sup> This includes family members, relatives and friends and excludes health professionals.

<sup>103</sup> The broad terms “mental ill-health”, “mental illness” and “mental health problems” are used interchangeably and refer to mental disorders but also include psychological distress, i.e. symptoms or conditions that do not reach the clinical threshold of a diagnosis within the classification systems but which can account for significant suffering and hardship, and can be enduring and disabling (OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris. [https://doi.org/10.1787/health\\_glance\\_eur-2018-en](https://doi.org/10.1787/health_glance_eur-2018-en)).

## EXPECTED RESULTS AND IMPACT

The expected results include the provision of psychological and psychosocial support to cancer patients, their carers and families, and a series of targeted interventions. This action will contribute to reducing the risk of long-term mental health problems among cancer patients and survivors, as well as their carers and families.

The development of a European Code for Mental Health will empower citizens, help raise awareness and improve their own health literacy.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – CR-g-23-19.01 Sub-topic (a): Mental health and Cancer  CR-g-23-19.02 Sub-topic (b): European Code for Mental Health	Q2 /2023	Sub-topic (a): EUR 8 000 000  Sub-topic (b): EUR 2 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Sub-topic (a): Civil society organisations (professional associations, patient organisations, foundations, NGOs and similar entities) with expertise in the field of mental health and cancer, academia and education establishments, research institutes, expert networks and established networks in the field of public health, and Member States’ authorities  Sub-topic (b) : Civil society organisations (professional associations, foundations,

		NGOs and similar entities) with expertise in the field of mental health, academia and education establishments, research institutes, expert networks and established networks in the field of public health, and Member States' authorities
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## **4 HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)**

### **4.1 STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS**

#### **HS-g-23-50.01-02 Call for proposals: action grants on the safety and quality of new substances of human origin (breast milk, faecal microbiota transplants)**

##### **POLICY CONTEXT**

The 2019 evaluation of the Union legislation on blood, tissues and cells identified a legal gap in terms of Regulation for some therapies made from substances of human origin (SoHO) that cannot necessarily be defined as blood, tissues, cells or organs. It concerns in particular therapies like human faecal microbiota transplants (FMT) and breast milk (BM), whose use entails the need to avoid transmission of diseases from donors. The revision of the Union legislative frameworks (blood and tissues and cells) aims to cover this gap and it plans to address safety and quality requirements for these therapies.

Dedicated guidelines on safety and quality have also to be implemented by a new group of actors with expertise on these therapies. It is estimated that around 200 new entities or establishments, working with BM or FMT, will be regulated under the new SoHO legislation. This action will help actors and establishments for the preparation of the implementation of these new legal requirements.

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, points (c) and (h), of Regulation (EU) 2021/522.

##### **OBJECTIVES, SCOPE AND ACTIVITIES**

This action aims to bring together sector professionals, for BM (subtopic (a)) and for FMT(subtopic (b)), and to facilitate the implementation of new SoHO guidelines and legislative requirements as well as the compliance with oversight tasks, in order to allow the safe, effective and qualitative use of these SoHO-based therapies.

The activities for both subtopics (a) and (b) are:

- a) building an expert forum on breast milk and an expert forum on faecal microbiota transplants;
- b) developing, for each SoHO-based therapy, a common set of draft guidelines on the basis of the expert forum and existing initiatives (e.g. professional societies' work, work in research actions);
- c) possible future updating of the guidelines, taking account of the new EU legislative framework;
- d) providing an implementation plan for establishments/entities in order to implement SoHO requirements, which will also consider the compliance with technical guidelines

- as well as with oversight provisions (entity and establishment authorisations, preparation process authorisations, inspections, vigilance and traceability); and
- e) training and dissemination programme.

These activities are to be developed taking account the commonalities and specificities of both SoHO-based therapies, i.e. BM and FMT.

#### **EXPECTED RESULTS AND IMPACT**

The two sub-topics should provide up-to-date guidelines on:

- a) technical safety and quality aspects for BM (subtopic (a)) and for FMT (subtopic (b));
- b) implementation of the legal requirements by establishments preparing these substances covered by both subtopics and applying therapies based on them.

They will also create a forum where key experts including Member States authorities can be engaged also in the future whenever the guidelines need to be updated, or when further advice is needed on their implementation.

Both subtopics will support the implementation of the new Union legislative framework on SoHO.

The result of the subtopic on faecal microbiota will consider the coherence with pharmaceutical actors/legislation, so that actors from both sectors (SoHO and Pharmaceuticals) can look into technical rules for faecal microbiota collected under SOHO and later to be used for manufacturing of pharmaceuticals.

The result of the subtopic on breast milk will consider the coherence with food actors/legislation, so that actors from both sectors (SoHO and food) can look into technical rules for breast milk collected under SOHO and later to be used for the manufacturing of food products.



**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals – Subtopic (a) HS-g-23-50.01 - Breast milk Subtopic (b) HS-g-23-50.02 - Faecal microbiotic transplants	Q1 /2023	(a) EUR 400 000 (b) EUR 400 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals (action grants)	HaDEA	(a) Civil society organisations (professional associations, foundations, NGOs and similar entities) with expertise in the field of neonatology.  (b) Civil society organisations (professional associations, foundations, NGOs and similar entities) with expertise in the field of gastroenterology.

## **HS-g-23-51 Call for proposals: action grants on facilitating organ paired exchange**

### **POLICY CONTEXT**

In Europe, patients are on waiting lists for long periods before receiving an organ transplant due to difficulties to find a compatible donor.

Kidney transplants can involve a living donor, usually a willing donor that is family related to the patient. When this donor does not match in terms of immunology to the patient, exchanges can be organised to match an incompatible donor-recipient pair with another one, and eventually create a series of matches. Such exchange schemes are being developed among some Member States to increase the probability of finding matches (in those countries where the enrolment of such pairs is allowed by national legislation). The development of a software including the matching algorithm (of donor-recipient pairs) is ongoing via a European Cooperation in Science and Technology (COST) action (funded by Horizon 2020 / IG15210 - Software for Transnational Kidney Exchange Programmes) and it is expected to be ready by the end of 2022.

In view of the scarcity of organs available for transplantation, there is a need to strengthen the exchange schemes among Member States, with a clear added value for European patients, as such exchange schemes can save the life of patients.

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, points (c) and (h), of Regulation (EU) 2021/522.

### **OBJECTIVES, SCOPE AND ACTIVITIES**

This action will apply the common algorithm for matching donor-patient pairs, among the participants and will develop its application by:

- a) developing the modalities for participating to the exchange schemes, including agreement and uptake by the different national allocation offices;
- b) feeding the algorithm with harmonised pair data via a common IT platform between participants;
- c) developing common support protocols among participants, covering all related aspects like oversight, governance, funding, follow-up of donors and patients, in order to allow that transplantations are taking place.

This action will roll out this common approach across national competent authorities, in charge of organ allocation.

### **EXPECTED RESULTS AND IMPACT**

The results are the following:

- a) a joint cross-EU allocation to facilitate Organ Paired Exchange on kidney transplants;

- b) development, agreement and use of common protocols, platforms and guidelines to increase the opportunities for patients looking for a kidney transplant;
- c) more and better treatment options for patients, and increase their quality of life.

The action will contribute to the recovery after the COVID-19 crisis which led to a significant amount of missed donations and transplant opportunities.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals – HS-g-23-51	Q1-Q2/2023	EUR 600 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals (action grants)	HaDEA	Member States’ authorities and professional organisations such as European organ exchange organisations.

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

**HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients**

**POLICY CONTEXT**

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.

Medical devices are subject to Regulation (EU) 2017/745, while IVDs are subject to Regulation (EU) 2017/746.

For the purpose of this action orphan devices<sup>104</sup> are medical devices, including in vitro diagnostic medical devices, that benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition.

At EU level, no specific legislation exists regarding the development and/or the market access of orphan devices which are in a large part intended for paediatric patients.

Paediatric patients usually differ from adults in terms of their size, growth, development, body chemistry, and disease propensity, adding to the challenges of paediatric device development. Costs related to market access, in particular clinical evaluation and conformity assessment, often render the development of paediatric devices economically not interesting. Innovation for paediatric patients therefore lags behind the advances made for adult devices.

This action supports the policy priority to support the implementation of the medical devices and in vitro diagnostic medical devices legislations 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, and supporting innovation regarding such 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.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

This action aims to support non-profit organisations or consortia that provide a platform for academic bodies, scientific societies, developer of devices, in particular SMEs, and NGOs with a specific interest in innovative paediatric devices to help foster and guide the development of orphan devices, for paediatric patients, in particular in areas of unmet medical needs. It takes inspiration from the Paediatric Device Consortia Grants Program of the US Food and Drugs Administration (FDA).

The activities may include, among other things, intellectual property advising; prototyping; engineering; laboratory and animal testing; grant-writing; and clinical investigation design.

The eligible entities should facilitate the development, production, and distribution of orphan devices, in particular for paediatric patients by:

- a) encouraging innovation and connecting relevant players (e.g. academia, scientific societies, users) with orphan device ideas with potential manufacturers;
- b) mentoring and managing orphan device projects through the development process, including product identification, prototype design, device development, and marketing;
- c) connecting developers of innovative devices and physicians to existing financing resources;
- d) assessing the scientific and medical merit of proposed orphan device projects;
- e) providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs; and

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<sup>104</sup> Exact definition of orphan devices is under discussion by the Medical Device Coordination Group (MDCG) - orphan device task-force.

- f) providing regulatory consultation to device developers in support of achieving CE marking for the orphan device.

A successful entity which could also be a consortium formed by the eligible entities can support orphan medical device advancement through all stages of development: concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization.

To accomplish this work, a successful entity should unite natural persons, association, or institutions to provide the following capabilities: knowledge of the clinical needs for orphan devices, business planning, regulatory advising, intellectual property protections and other legal expertise, as well as scientific, engineering, pre-clinical, and clinical capabilities.

#### **EXPECTED RESULTS AND IMPACT**

This program is intended to promote the development of innovative orphan devices for paediatric patients, with a particular focus on devices responding to unmet medical needs.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposal - HS-g-23-65	Q2-Q3/2023	EUR 500 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for proposals (action grants)	HaDEA	scientific societies, academia, possibly also including SMEs and NGOs with a particular interest and expertise in the area of the action

## **HS-g-23-62 Direct grant to EU reference laboratories for the Union contribution on in vitro diagnostic medical devices**

### **POLICY CONTEXT**

EU reference laboratories (EURLs) are a crucial new type of scientific body in the diagnostics sector put in place by Regulation (EU) 2017/746 on in vitro diagnostic medical devices. These laboratories will 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 will be funded by fees from notified bodies and Member States but a significant part may not be covered by fees. The 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.

The action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and encouraging innovation regarding such products (Article 3, point (c) 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**

This action will support the functioning of the EU Reference Laboratory network mandated by Article 100(5) of Regulation (EU) 2017/746 and the associated activities: application of coordinated methods, procedures and processes, developing, applying and maintaining a peer review system, organising regular quality assessment tests, etc.

It 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 rigorous 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.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants - HS-g-23-62	Q2-Q3/2023	EUR 1 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to the EU reference laboratories in accordance with Article 195, first paragraph, point (d) of Regulation (EU, Euratom) 2018/1046	HaDEA	EU reference laboratories

### 4.3 GLOBAL HEALTH

## **HS-g-23-71-01 Direct grant to Member States' authorities: global health impact**

### **POLICY CONTEXT**

EU leadership has played a key role in the fight against the pandemic at home and abroad, not least through the Team Europe approach, with the EU and Member States contributing through their well-defined competences. Strengthening that leadership is essential to maximise the impact on global health of EU important substantive and financial contributions and to defend its core interests in a complex geopolitical environment<sup>105</sup>.

There is wide consensus in EU institutions and Member States that we must improve Team Europe coordination to speak and act with one powerful and influential voice. Following the rich ideas from Member States, an overarching coordination system will be established to better share information; define EU positions; and take political and financial action to address global health challenges. Recognising that global health depends on actions in several sectors, the action will ensure coordination between sectors within Member States, EU institutions and Commission services, consistent with the health in all policies principle.

Specialised platforms are needed to facilitate the sharing of information, and coordination of Team Europe actors in key focal points (Brussels, Member State capitals, Geneva and New York). An on-going Czech Presidency initiative will be a key enabler for coordination along these lines.

This arrangement is essential to collect views from Member States, including through periodic surveys on specific topics, and consolidate common positions.

It will be essential to coordinate political and financial efforts of the EU and Member States' actors, including financial bodies, to help delivering on this strategy's priorities. This requires a system that maps all such efforts, identifies the Team Europe actions and investments required to support effective action at the global level, and ties means to priorities.

A final and important element linked to Team Europe coordination is improved communication, so that Team Europe global health efforts receive the recognition they deserve. Member States suggested a communication mechanism specifically catered towards the strategy, using Team Europe as trademark for the effective actions in health. The permanent mapping of efforts and financing streams by Team Europe will provide a wealth of facts to illustrate intensive efforts, and the EU leadership.

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

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<sup>105</sup> [reference: the Global Health Strategy if adopted timely].



The action implements all EU4Health Programme’s general 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 (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**

To strengthen EU global health leadership and fully exploit the powerful Team Europe approach, speaking and acting with a single voice, closely coordinating actions and financial efforts to maximise EU impact and strengthening communication on the vast Team Europe contribution to health globally.

#### **EXPECTED RESULTS AND IMPACT**

The result of this action will:

- a) strengthen EU global health leadership and solid governance arrangement with the Member States;
- b) maximise the impact on global health of EU financial contributions;
- c) improve “Team Europe coordination”, while ensuring coordination between sectors within Member States, EU institutions and Commission services, consistent with the health in all policies principle;
- d) establish specialised platforms to facilitate the sharing of information, and coordination of Team Europe actors in key focal points (Brussels, Member State capitals, Geneva and New York);
- e) produce periodic surveys on specific topics, and consolidate common positions;
- f) create a system to map political and financial efforts;
- g) strengthen EU capacity and expertise in global health;
- h) improve communication within and beyond EU.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – HS-g-23-71-01	Q1/2023	EUR 4 700 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grants to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU,	HaDEA	Member States’ authorities

Euratom) 2018/1046		
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## **5 DIGITAL (DI)**

### **DI-g-23-75 Direct grants to Member States' authorities: increase health data semantic interoperability and build national capacity on health terminologies**

#### **POLICY CONTEXT**

There is currently a fragmentation of standards used to express clinical concepts, including the use of national specific terminologies. This hampers the semantic interoperability of health data. Thus, there is a need to promote the use of international standard terminologies to support health professionals expressing clinical meaning. This is even more important considering the great potential of the reuse of health data to improve health research outcomes, access to health innovation and policy and regulatory decisions. Once the proposed European Health Data Space Regulation is adopted, this need would become even more urgent when having in sight that health data collected for healthcare purposes has great potential for secondary uses. The use of international standard terminologies increases the potential for re-use of health data.

This action aims at supporting Member States in the continuous convergence towards the use of international standard terminologies, namely Systematised NOmenclature of MEDicine - Clinical Terms - SNOMED CT. This could allow, in the end, that the EU patients have their data available in all the EU languages and can share them with healthcare professionals of their choice when travelling abroad as well as increase data quality for research purposes.

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

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

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

To support Member States' authorities in joining SNOMED international (joining fees) and acquiring or renewing the annual licenses (membership fees) for the use of the SNOMED CT.

#### **EXPECTED RESULTS AND IMPACT**

The action is expected to:

- a) SNOMED CT will be available for use by health professionals in the majority of Member States enable the development of comprehensive high-quality clinical content in electronic health records;
- b) increase the semantic interoperability of health data and thus facilitate the cross-border exchange and re-use of health data;
- c) facilitate patient access to and translation of their health data.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – DI-g-23-75	Q1/2023	EUR 5 400 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States in accordance with Article 195 point (c) of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States’ authorities

**DI-g-23-77 Direct grants to Member States’ authorities: development and enhancement of MyHealth@EU services, including vaccination card services**

**POLICY CONTEXT**

As performed currently, patient identification in MyHealth@EU suffers from some shortcomings. Health professionals need to enter manually patients’ identification data and document identifiers. This is burdensome and error-prone (person or document identifiers have commonly over 10-digit long). Additionally, there is no electronic notification to or request for confirmation by the patient when their data is accessed.

In particular, in the current ePrescription services in MyHealth@EU a person’s identification data needs to be entered manually by a pharmacist. To avoid manual entry of data and to improve security, and data protection, several Member States have introduced the use of barcodes in their national ePrescription systems. In these national implementations, the barcodes are printed on paper or shown through mobile apps. However, the barcodes of different Member States are not interoperable and therefore not used in MyHealth@EU, resulting in situations where barcodes issued by one Member State are not understood by a pharmacy system in another Member State.

In many Member States, people can directly access (without the need for a health professional mediation) their Patient Summaries or parts thereof, such as vaccination data. Individuals can share the data with a health professional in another Member State by showing the data on their mobile phone, however, they are unable to prove the authenticity of this data. The

current MyHealth@EU services always rely on the initiation of access to data by health professionals and do not enable citizens to directly share their health data with people and organisations of their choice (e.g. health professionals not connected to MyHealth@EU) or to prove the authenticity of the data (e.g. a vaccination certificate). Only health professionals in organisations connected to MyHealth@EU can access these health information services. However, the need for people to be able to share their health data is broader, and technologies for this are being currently designed by G7, G20 and the WHO, based on digital health trust networks.

As shown by the EU Digital COVID Certificate (EU DCC) implementation, today's widespread use of smartphones and QR code technology can be used to overcome most of the limitations described before. The know-how and solutions acquired with the implementation of the EU DCC should be adjusted and put to use to enhance MyHealth@EU services and functionalities. In particular, the use of the EU DCC technology in connection with MyHealth@EU services would be fundamental for the development of interoperable vaccination card functionalities by Member States.

Therefore, there is a need to support Member States in deploying these services at the national level. Through this support, the European service infrastructure of MyHealth@EU will enable scenarios based on the use of smartphones, including QR code technology, taking into account the examples developed in the context of the EU DCC. This should also support the development of vaccination card services, based on the outcomes of the EU vaccination card feasibility study.

This action complements procurement action DI-p-23-76 on enhancing MyHealth@EU core services with scenarios supporting patients' access to their health data, taking into account the developments in the context of EU DCC. This action (DI-g-23-77) covers the development and deployment of new services to support patients' access, on the basis of the EU DCC technology framework, at the level of the national contact points for eHealth, that is at the level of the generic services. Action DI-p-23-76, on the other hand, will cover the development and deployment activities needed at the level of the central services, i.e. those provided by the European Commission. Both are needed for the cross-border services to function in the MyHealth@EU infrastructure.

The award of a direct grant as referred to in Article 13 (5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by the Member States' authorities that have the required competences and responsibilities 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) of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objective of this action is to pilot the implementation, integration, deployment and operation of Member State services in MyHealth@EU taking advantage of widespread use of smartphones and QR code technologies, based on the example of EU Digital Covid Certificate, covering the ePrescription, Patient Summary and vaccination card services.

This action could support one or more consortium(s) deploying and running pilots for one or more use cases above mentioned.

#### EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- a) improvement of usability and security of MyHealth@EU services (including ePrescription, patient summary and vaccination card services), based for example on the EU DCC technology and trust framework;
- b) integration, deployment and piloting by national contact points for eHealth of vaccination card services based on the common services provided within MyHealth@EU;
- c) enhancement of mobile digital health services for citizens and their integration with EU Digital Identity Wallet functionalities being developed following the proposed update of the eIDAS Regulation;
- d) possibility for citizens to share their health data with health professionals who cannot currently access MyHealth@EU, depending on the national legislation.

#### INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants – DI-g-23-77	Q2-Q3/2023	EUR 4 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States in accordance with Article 195 point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

#### **DI-g-23-79 Direct grants to Member States' authorities: preparatory activities for the reuse of data in the proposed European Health Data Space**

##### POLICY CONTEXT

The Data Governance Act<sup>106</sup>, under its Article 7, sets out the provision for competent bodies to support the re-use of public sector data protected, as it is personal data or commercially sensitive. The proposed European Health Data Space (EHDS) builds upon the Data Governance Act and specifies the roles of competent bodies in health as health data access

<sup>106</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R0868>.

bodies. In the health area, several Member States have set up health competent data access bodies (such as Finland, France, Germany or Denmark) and other Member States aim to set up such structures. They provide core services for a common ICT infrastructure and crosscutting services such as terminology, interoperability. In parallel to that, the Joint Action Towards the European Health Data Space (TEHDAS) aims at developing European principles for the secondary use of health data, and initiated its activities in June 2020.

However, there is a need to support and promote the establishment and strengthening of such entities supporting the re-use of health data for research, innovation and policy making, including for statistical purposes. This could be achieved, by expanding core services, nodes and connections between health data access bodies, and related services for the development of the proposed EHDS for secondary uses of health data in all Member States.

Health Data Access Bodies (HDABs) are expected to play a key role in the future digital governance in light of the proposed EHDS Regulation, ensure communication towards citizens (i.e. by reporting on data access applications, permits granted, audits, and other activities), and strengthen public health information system beyond COVID-19 (i.e. by supporting public bodies with this mandate).

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

The joint 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) of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objective of this joint action is to prepare the ground for the implementation of common measures enabling the secondary use of health data in the proposed EHDS, building on the work of national and EU initiatives and projects, such as TEHDAS joint action and the HealthData@EU (EHDS2) pilot for an EU infrastructure ecosystem for the secondary use of health data for research, innovation, policy-making and regulatory purposes.

#### **GENERAL ACTIVITIES ARE:**

- a) preparing the ground for, and supporting the legislative developments of the proposed European Health Data Space for the implementation of secondary use of health data, taking into account other complementary actions in this area;
- b) continuously collaborating with other actions relevant for secondary use of health data (for example, through a project forum).

#### **SPECIFIC ACTIVITIES ARE:**

Preparing guidelines on the tasks and common policies of Health Data Access Bodies on:

- a) minimum categories of electronic data for secondary use;
- b) policies related to fees and penalties for non-compliance with the EHDS rules;
- c) cooperation and collaboration with other parties, including with authorised participants in EHDS;

- d) reporting including obligations towards natural persons;
- e) limitations on the reuse of health data based on the purposes sought;
- f) data enrichments and linkage between datasets;
- g) data altruism in health;
- h) obligations towards natural persons;
- i) international and third country access and transfer of personal and non-personal electronic health data.

Preparing guidelines for data holders on:

- a) how to fulfil the duties regarding datasets description;
- b) how to make electronic health data available;
- c) how to ensure access to non-personal electronic health data.

Preparing guidelines for data users on:

- a) how to fulfil the duties regarding data access applications;
- b) how to fulfil the duties regarding processing electronic health data in a secure processing environment;
- c) how to fulfil the duties regarding research outcomes.

Preparing technical specifications for:

- a) procedures and formats relating to issuance of data permits, data requests and multi-country data access applications procedures, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests;
- b) data minimization and data de-identification (anonymisation and pseudonymisation, synthetic data);
- c) the implementation of common IT infrastructure, including the connection with 'authorised participants';
- d) secure processing environments (services, interoperability, security and data privacy);
- e) management systems to record and process data access applications, data requests and the data permits issued and data requests answered;
- f) dataset catalogues publicly available to register and facilitate the discovery of health datasets available for secondary use.

## **EXPECTED RESULTS AND IMPACT**

The expected results are guidelines and technical specifications for common aspects of the implementation of the proposed EHDS, including:

- a) increased preparedness for the implementation of the proposed EHDS;
- b) better coordination of Member States' joint efforts towards the secondary use of health data;
- c) reduced fragmentation on policies and practices for secondary use of health data.



## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – DI-g-23-79	Q1/2023	EUR 4 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant (joint action) to Member States in accordance with Article 195 point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

## 6 OTHER ACTIVITIES (OA)

### **OA-g-23-82 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 2021/522 during the rotating Presidency of the Council with two conferences to be organised in 2023 and early 2024.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

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

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

#### **EXPECTED RESULTS AND IMPACT**

The Member States holding the rotating Presidency of the Council are the beneficiaries of the grants to be awarded without a call for proposals based on Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046. The form, topic and expected results are established by the Presidency in agreement with the Commission. These events, which are highly political in nature, and which need representation at the highest level both from national authorities and the EU, are to be organised exclusively by the Member State holding the Presidency. Given the unique role of the Presidency among EU activities, the Member State responsible for the organisation of the event is considered as a de jure monopoly.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Direct grants – OA-g-23-82	2023	EUR 200 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Direct grant to Member States in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Presidency of the Council of the European Union

**OA-g-23-89 Call for proposal: action grants to contribute to the organisations of conference and events****BACKGROUND**

The work programme will support the organisation of conference and events which will meet the objectives of Regulation (EU) 2021/522 during 2023.

There is a need to (i) timely identify upcoming health challenges and involve all interested parties such as citizens, patients, practitioners, scientists, policy makers from local, regional, and EU level, in finding possible solutions and alternative ways to address such challenges; (ii) provide information to individuals for preventing and responding to diseases; (iii) join efforts with the beneficiaries of the EU 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 fora to facilitate the exchange of ideas and development of feasible solutions.

The action will support the EU4Health Programme's general objectives 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, EU-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 EU level. The events will promote and contribute to the development and implementation of the European Health Union touching in a comprehensive way the most salient health issues and EU health priorities.

Up to three proposals of different sizes will be accepted. Priority will be given to proposals covering several types of health challenges in several Member States and beyond the EU. Proposals should include considerations and state-of-the art activities to facilitate the exchange of ideas and identification of Union-wide and/or global solutions to major health challenges.

These conferences are an opportunity for a discussion on how to work better together at EU level on one or more health-related topics and will involve Member States' authorities 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 non-profit making 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, making reference to distribution by Member States or third countries associated to the EU4Health programme, organisation and type of expertise.

The action will deliver at least three different high-level events that will promote and 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.

The events should include high level speakers, a representative number of participants from all relevant fields to 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, but will focus on current cross-cutting Union policy issues.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
Call for Proposals – OA-g-23-89	Q1-Q2/ 2023	EUR 450 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Open call for Proposals (action grants)	HaDEA	Public or non-profit entities with expertise on organising events in public health domain

## **B. PROCUREMENT**

The overall allocation reserved for procurement contracts and administrative arrangements in 2023 amounts to EUR 176 428 071.

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

In 2023, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts) or administrative arrangements (including service level agreements, co-delegations and memoranda of understanding) with other Commission services (e.g. JRC, DIGIT, ESTAT, COMM) or European bodies (e.g. European Environmental Agency) to support priorities in the following thematic areas.

### **ACTIONS WITH A COST OF EUR 20 000 000 OR MORE**

#### **1. CRISIS PREPAREDNESS (CP)**

##### **CP-p-23-15 Support to speed up the development of, access to and/or uptake of innovative technologies and critical medicines (HERA)**

In accordance with its work plan 2022 (item 1.11), HERA is currently establishing the list of critical medical countermeasures (MCM) required to improve EU preparedness and response to serious cross-border health threats. Based on this list, including both existing and in-development MCM, HERA will identify the most promising and innovative technologies for diagnostic, preventive and therapeutic purpose, whose development, access or uptake should be supported. Furthermore, in case of a future public health emergency, the Commission is tasked with establishing a list of crisis-relevant medical countermeasures and raw materials.

In addition, the recent health emergencies have clearly demonstrated that unilateral responses are limited in reach and results, therefore HERA plans to implement part of this action in collaboration with global actors to ensure availability and access of needed medical countermeasures both, in the Union but also in third countries. Parts of this action will provide support to the development and access to the market of medical countermeasures in a joint effort with the Biomedical Advance Research and Development Authority (BARDA) in order to maximise the efficiency of investments in the field of medical countermeasures.

The action is also expected to support the setting up of development and sustainable production pipelines for select crisis medicines by linking coordination mechanisms for more integrated regulatory and financial decision making processes starting from an early stage of the development (phase IIa). The action will support national regulatory bodies (clinical trials and medicines regulators, HTA bodies and EU health care payers) to carry out and coordinate their assessments. Early and continuous involvement is expected to result in higher-quality

data generation to be used for multiple decisions. This, together with improved agency-company interaction and familiarity with the product file from early stages of development, might expedite and broaden access to critical crisis medicines. In appreciation of the resource constraints at national level, the action would focus on select crisis medicines that have been prioritized for development by HERA in close cooperation and agreement with Member States. The implementation of this action will be supported by a third party contractor as secretariat to ease associated administrative burden and ensure adequate follow-up.

This action is intended to allow HERA to support the development, access and uptake of MCM, including medicinal products, medical devices, in vitro diagnostic devices, PPE and/or other health technologies, necessary to improve preparedness and response to serious cross-border health threats. This also includes:

- a) supporting late stage clinical trials, clinical investigations, performance evaluation or similar studies for MCMs needed to respond to health emergencies; in particular, this action will allow the mobilisation of funds to speed up development, market authorisation and access to MCM in the context of emergencies and will support one or several trials or other studies that are necessary to provide evidence of safety and efficacy of one or several MCM that have been identified as critical to prepare and respond to cross-border health threats. It is expected that this action will also support the purchase of MCM according to Article 9 of Regulation 2021/522 and other related activities under the remit of HERA;
- b) supporting the development of medical countermeasures for epidemic and pandemic preparedness, in particular for a new generation of COVID-19 vaccines; in particular, this action will support the development of such vaccines, building on the extensive portfolio of COVID-19 vaccines, and addressing some of the limitations of current vaccines including the development of manufacturing and infrastructure capacities that could be key to ensure access to safe and effective next generation vaccines. This could include potential pan-coronavirus, or combination vaccines to respond to current and future health threats;
- c) supporting the development and access to innovative and repurposed MCMs considered as a priority. In particular, this action will support economic operators developing, manufacturing and/or putting on the market innovative and/or repurposed MCM or treating, preventing or diagnosing priority health threats (including when there are no other alternatives available for treating, preventing or diagnosing priority health threats or where innovative and/or repurposed MCMs can significantly improve the existing landscape to address a specific threat by providing safer or more effective solutions). The relevant countermeasures will be selected on the basis of the prioritisation exercises carried out by HERA (i.e. on health threats and the list of critical MCM). The identification of the critical MCM for priority health treats can be carried out only by HERA or as a common effort by HERA and other international partners (e.g. BARDA) to ensure that joint investments in the late-stage development of MCM effectively speed up the availability and accessibility to products considered critical at global level;

- d) supporting the setting up of development and sustainable production pipelines by coordinating relevant actors at national level building on existing EU structures. In particular, by supporting and coordinating different actors in the Member States in their efforts to accelerate the access to market of priority medicines for cross-border health threats.

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 (Article 3, point (c)) 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 framework contracts and/or service contracts to support to speed up of development, access and/or uptake of innovative technologies

Indicative budget for this thematic area: EUR 84 000 000

Implementation by: HaDEA

### **CP-p-23-16 Support innovation and access to antimicrobials (HERA)**

Antimicrobial resistance (AMR) is a major threat to health, which was associated with 5 million deaths globally in 2019<sup>107</sup> 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 (AMR MCM) existing and in development AMR MCM, 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 MCM. The activities to be covered by this action aim to promote the development, availability and access to preventive, diagnostic and therapeutic MCM for AMR.

The activities to be covered by this action aim to promote the development, availability and access to preventive, diagnostic and therapeutic MCM for AMR, including:

- a) coordinating a network that will provide e.g. recommendations, reports and related information, notably in preparation of procurement(s) of MCM or reservation contracts (including specific provisions to be potentially included in the contract templates such as revenue guarantees) as well as their implementation. This can include for instance a description of the eligible antimicrobials, the requirements

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<sup>107</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext).

for national access and stewardship, the payment schemes, the estimated social value of the antibiotics as well as manufacturing and supply chain considerations;

- b) reserve capacities for the production or access to targeted AMR MCMs for products with a Union-wide marketing authorisation but also on products under development on the basis of the HERA preparatory actions implemented through the EU4Health 2021 work programme.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and 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 call(s) for tender for either framework contracts and/or service contracts.

Indicative budget for this thematic area: EUR 22 000 000

Implementation by: HaDEA

## **ACTIONS WITH A COST BELOW EUR 20 000 000**

### **1. CRISIS PREPAREDNESS (CP)**

#### **CP-p-23-14 Support to the Commission on identifying priority threats and medical countermeasures (HERA)**

As announced in the Commission Communication<sup>108</sup> introducing HERA and the HERA work plan 2022<sup>109</sup>, 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 will be complemented by the development of a list 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 to identify and prioritise of biological, chemical, nuclear/radiological agents, as well as unknown threats of natural or deliberate origin, and to support the mapping of and assessment of availability and

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<sup>108</sup> [Communication on introducing the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union \(europa.eu\).](#)

<sup>109</sup> [HERA Work Plan 2022 \(europa.eu\).](#)



accessibility to medical countermeasures<sup>110</sup>. 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: open call for tenders for framework contract(s)

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

### **CP-p-23-20 Continuous support to existing wastewater activities including the establishment of an EU 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 super sites and to be able to enlarge the number of supersites. This action aims to ensure continuation and expansion of ongoing activities.

This activity will be implemented taking into consideration action CP-g-23-18. Through an administrative agreement between HERA and DG JRC, this action aims to ensure continuation and expansion of ongoing activities, including the Digital European Exchange Platform; an active and regular Engagement Mechanism with the Community of Practices; and the EU Sewage Sentinel System for SARS-CoV-2. Appropriate QA/QC measures such as the availability of appropriate metrological reference materials and proficiency testing schemes can be also necessary and their development should be promoted.

In addition, this action should cover testing of wastewater samples on the request of the Commission through: 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 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

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<sup>110</sup> Relevant stakeholders and projects such as the HERA laboratory network are expected to be involved.

serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522

Indicative type of contracts/supply: administrative arrangement with DG JRC, open call(s) for tender for framework/service contract(s) the testing wastewater samples at the request of the Commission.

Indicative budget for this thematic area: EUR 2 500 000

Implementation by: HADEA

### **CP-p-23-21 Support to epidemic intelligence from open sources (HERA)**

Epidemic Intelligence from Open Sources (EIOS) is a web-based system designed to augment and accelerate global public health intelligence activities. It is the result of a collaboration between the WHO and the DG JRC. While EIOS is a flagship initiative of the WHO Berlin Hub for Pandemic and Epidemic Intelligence, DG JRC is responsible for the development and maintenance of its core system. EIOS basic features are to scrape and filter content published online, to help users identify and categorise relevant signals and information, which they share within their user community. EIOS will support HERA to fulfil its mandate but, in order to extend the scope beyond health threats in order to cover medical countermeasures, some technological developments are needed to improve the existing functionalities. This action aims at supporting the technological development of the EIOS system.

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: administrative arrangement with DG JRC

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: HaDEA

### **CP-p-23-24 Purchase of medical countermeasures (MCM) in emergency situations (HERA)**

The action aims to procure and supply essential crisis-relevant products in a manner that complements Member States' reservation and stockpiling actions, as well as the rescEU strategic stockpiles developed under the framework of the Union Civil Protection Mechanism (UCPM). In particular, it will reserve capacities for the production and/or purchase of MCM

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 EU level. 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-wide 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 MCM or reserve manufacturing capacity and assign these capacities for orders placed by the EU contracting authorities and/or the Commission.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and supports 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 MCM.

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

Implementation by: HaDEA/HERA

### **CP-p-23-10 Table-top exercise on cross border health emergencies (HERA)**

This action aims at the design, planning and implementation of table-top exercises on preparedness and response to public health emergencies, in particular those with a cross-border nature (e.g. pandemic, epidemic, CBRN), and regarding medical countermeasures.

Participation and consultation with relevant EU services, such as ECDC, and international organisations should ensure, where possible, synergies and efficiencies. Also selected third countries could be consulted and involved in the exercise, notably for sharing expertise and best practices.

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: open procedures for either framework contract(s) and/or service contract(s) for the organisation of table-top exercises on cross-border health threats.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

### **CP-p-23-11 Gap analysis on knowledge and skills (HERA)**

This action aims to evaluate training needs of specific target groups on preparedness and response related to medical countermeasures. This may include the development and management of medical stockpiles, EU public procurement rules and pharmaceutical Regulation to assist on the purchase of medical countermeasures, needs and gaps in data collection, forecasting and management of stocks and procurement at different levels and policies in support of availability and accessibility of MCM. This action may also identify potential gaps in Member States knowledge and skills, as well as existing training catalogue available to different Member States, to support the development of HERA's training programme.

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: open procedures for either framework contracts and/or service contracts for a gap analysis on knowledge and skills.

Indicative budget for this thematic area: EUR 400 000

Implementation by: HaDEA

### **CP-p-23-12 Training on management of medical countermeasures: public procurement in times of crisis (HERA)**

In time of crisis, with high uncertainty and a rapidly changing context, the provision of the necessary healthcare services is more directly dependent on public procurement strategies and available procurement instruments, as shown by the COVID-19 pandemic. This action aims at the design, planning and implementation of a masterclass training on the management of public procurement for medical countermeasures during a public health crisis.

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: open call for tender for either framework contracts and/or service contracts for the provision of training on management of medical countermeasures.

Indicative budget for this thematic area: EUR 600 000

Implementation by: HADEA

**CP-p-23-05-02 EU reference laboratories (I): support the set-up and operation of the EU reference laboratories for the Diagnostics of Human Pathogens Network ((Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU <sup>111</sup>))**

The Regulation of the European Parliament and of the Council on serious cross-border threats to health defines that the Commission may 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.

Coordinated EU laboratory support strengthens preparedness, crisis management and outbreak response capacities in Member States thereby representing an area with clear EU-added value. Sustainable EU reference networks of microbiology laboratories also ensure an adequate response to biological threats, including to intentional release and bioterrorism, thus contributing to a high level of protection to biological agents and health security in Europe.

The EU has supported Member States' laboratory cooperation under the Health programme, most recently through the EMERGE joint action (Efficient response to highly dangerous and emerging pathogens). This joint action ensures cooperation between 40 diagnostic laboratories specialised on highly-pathogenic agents, with health security relevance. Currently, this network is part of the SHARP joint action, which works on improving preparedness and International Health Regulations<sup>112</sup> (IHR) implementation, including laboratory preparedness.

Moreover, support for harmonisation of laboratory diagnostics, antimicrobial susceptibility and molecular typing methods, multicentre method validation, technical capacity mapping, training of laboratory staff, and continuing quality assessment of laboratory testing are provided by the ECDC through coordination of Union-wide networks of microbiology laboratories.

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<sup>111</sup> 2020/0322 (COD), not yet published in the Official Journal.

<sup>112</sup> International Health Regulations (who.int)

The EU reference laboratories<sup>113</sup> shall be responsible to coordinate the network of national reference laboratories. The network of EU reference laboratories shall be operated and coordinated by the ECDC, in cooperation with the WHO Reference Laboratories, and coordination with the laboratory network managed by HERA will be ensured.

Under this action preparatory work will be carried out for the establishment of the EU reference laboratories for human pathogens. The results of this activity will feed into CP-g-23-05-01 EU Reference Laboratories II.

This action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (b) and (c), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service

Indicative budget for this thematic area: EUR 400 000

Implementation by: HADEA

### **CP-p-23-08 Setting up of an advisory committee (ad-hoc operation in case of potential emergencies) (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU<sup>114</sup>)**

In accordance with Article 23 of Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, the Commission may formally recognise a public health emergency at EU level, including pandemic situations where the serious cross-border threat to health in question endangers public health at EU level, and establish an advisory committee on public health emergencies which can be asked to advise the Commission or the Health Security Committee on whether a threat constitutes a public health emergency at EU level.

The aim of this action is to establish a structure and processes for the recognition of a public health emergency at EU level with the advisory committee to be able to promptly seek advice should the need arise. The established advisory committee will operate ad-hoc and/or in case of emergency.

The recognition of a public health emergency at EU level will activate the response component including the activation of the Commission's Health Emergency Operation Fund

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<sup>113</sup> <https://www.ecdc.europa.eu/en/publications-data/core-functions-microbiology-reference-laboratories-communicable-diseases>.

<sup>114</sup> 2020/0322 (COD), not yet published in the Official Journal.

(HEOF) and the EWRS response modules on situation awareness and incident management to support crisis management that is coordinated with the Health Security Committee.

This action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (b), 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

### **CP-p-23-02 Feasibility study on integrated surveillance systems on Antimicrobial Resistance (AMR) and antimicrobial use from the human, veterinary and plant production and environmental sectors**

AMR is an increasing global health threat and responsible for an estimated 33 000 deaths in the EU/EEA. The 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. AMR surveillance is the basis for combating antimicrobial resistance. There are global recommendations to engage in an integrated AMR One Health approach for surveillance systems, which entail the integration of findings on drug-resistant microorganisms in animals, humans, plants, and the environment. This process involves sharing data and information across sectors for a more effective and coordinated response to combating AMR. 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. The data these surveillance systems provide can enhance the understanding of the complex epidemiology of AMR to guide policy recommendations and develop interventions to respond to AMR risks before they become large-scale emergencies.

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

Indicative type of contracts/supply: open procedure for a service contract for a study on market research and mapping of innovative diagnostic testing solutions.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

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

### 2.1 TOBACCO POLICY

#### **DP-p-23-26 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 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 Commission is running an overarching evaluation of the legislative framework for tobacco control (including Directive 2014/40/EU of the European Parliament and of the Council<sup>115</sup>, Directive 2003/33/EC of the European Parliament and of the Council<sup>116</sup> and other related tobacco control policies across the Union). This evaluation process and any resulting steps will be carried out in line with the Better Regulation principles.

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 EU market, new virtual environments (including web shops and information society services such as social media) have surfaced and new public health interference strategies of tobacco and related industries have emerged.

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 (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service, use of existing or new framework contracts.

Indicative budget for this thematic area: EUR 1 200 000

Implementation by: HaDEA

#### **DP-p-23-27 Special Eurobarometer: attitudes of Europeans towards tobacco and related products**

The Union regularly carries out public opinion polls to monitor Europeans' attitudes to a range of tobacco-related issues. The general aim of these surveys is to assess the prevalence and

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<sup>115</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2002/37/EC (OJ L 127, 29.4.2014, p.1).

<sup>116</sup> Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ L 152, 20.6.2003, p.16).



pattern of tobacco and electronic cigarette use, exposure to smoke in public places, to explore the motivations for smoking, and to help identify measures to reduce the number of smokers in the Union. Regular Eurobarometers are important tools for effective and accurate monitoring of the Tobacco Products Directive and for assessing whether EU actions in tobacco control are effective.

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 (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangements, framework contract

Indicative budget for this thematic area: EUR 500 000

Implementation by: DG SANTE

### **DP-p-23-28 Tobacco Products Directive - Characterising flavours: operation of technical group**

The implementation of Directive 2014/40/EU entails the operation of a technical group of sensory and chemical assessors ('the technical group') assisting the Independent Advisory Panel 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 is being 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 technical group will provide the panel with an assessment of the sensory and, where appropriate, chemical properties of the test product as part of the procedure laid down in Commission Implementing Regulation (EU) 2016/779<sup>117</sup> and Commission Implementing Decision (EU) 2016/786<sup>118</sup>.

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 (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: existing framework contract.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

### **DP-p-23-29 Tobacco Products Directive: operation of IT databases**

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<sup>117</sup> Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour (OJ L 131, 20.5.2016, p.48).

<sup>118</sup> Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour (OJ L 131, 20.5.2016, p. 79).

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 IT service will help the Commission to 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. Through this action the Commission will also oversee and monitor the system for tracking and tracing of tobacco products and audits providers of primary and secondary repositories.

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 (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service, administrative agreement, existing framework contract.

Indicative budget for this thematic area: EUR 1 700 000

Implementation by: DG SANTE

## **DP-p-23-30 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 DG JRC as the basis for continuation of the mutual Administrative Arrangement in this area.

It should further support the Directive 2014/40/EU implementation and its monitoring through technical expertise and laboratory capacity (in particular to analyse the ingredients of tobacco products and e-cigarettes) of DG 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 objectives defined in Article 4, points (a) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/ supply: administrative arrangement

Indicative budget for this thematic area: EUR 100 000

Implementation by: DG SANTE

### 3. CANCER (CR)

#### 3.1 PREVENTION OF CANCER, CANCER SCREENING AND QUALITY OF LIFE OF SURVIVORS

##### **CR-p-23-41 Development of EU guidelines and quality assurance scheme for lung, prostate and gastric cancer screening**

On 20 September 2022, the Commission adopted a proposal for a Council Recommendation on strengthening prevention ‘A new EU approach on cancer screening’ replacing Council Recommendation of 2 December 2003 on cancer screening 2003/878/EC<sup>119</sup>. In addition to the cancer screening programmes for breast, colorectal and cervical as recommended under the 2003 Council Recommendation, the Commission proposal recommends screening for lung, prostate, and under certain conditions, gastric cancer. Through the Commission initiatives on Breast and Colorectal Cancer<sup>120</sup>, a system and methodology for the development of EU guidelines for cancer screening and treatment including also a Quality Assurance Scheme, has already been developed. Based on this existing methodology, guidelines for the screening of lung, prostate and gastric cancers will be developed as indicated in the Commission proposal for the Council Recommendation. 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.

This action supports the implementation 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 defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangement or service contract

Indicative budget for this thematic area: EUR 7 500 000

Implementation by: HaDEA

##### **CR-p-23-39 Evaluation study: Use of sunbeds and cancer risk**

Reducing exposure to hazardous substances and radiation is one of the objectives of the prevention pillar of the Europe's Beating Cancer Plan. The Commission committed itself to explore measures on exposure to ultraviolet radiation, including from sunbeds, which increases the risk of melanoma, the most serious form of skin cancer. Accordingly, there is a need to address this topic and identify the appropriate measures to address human health risks associated with the use of sunbeds at the EU level. The study will build on the ‘Opinion on

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<sup>119</sup> [https://eur-lex.europa.eu/procedure/EN/2022\\_290](https://eur-lex.europa.eu/procedure/EN/2022_290).

<sup>120</sup> [European Commission Initiatives on Breast and Colorectal Cancer | Cancer screening, diagnosis and care \(europa.eu\)](#).

Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes' delivered by the Scientific Committee on Health, Environmental and Emerging Risks<sup>121</sup> in 2016.

This action supports the implementation 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 defined in Article 4, points (a) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: DG SANTE / HaDEA

### **CR-p-23-43 Study on the quality of life of cancer survivors**

There is a lack of evidence on differences and disparities in the quality of life of cancer survivors between Member States and regions. This action will aim to close this gap by triangulating data from different sources. It will assess the existence and effectiveness of initiatives implemented by the Member States and regions to improve the quality of life of patients and survivors<sup>122</sup>.

This action supports the implementation 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 defined in Article 4, point (a), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open procedure, service

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: HaDEA

### **CR-p-23-27.2 Special Eurobarometer: Attitudes of Europeans towards alcohol consumption as well as on the labelling of alcoholic beverages with respect to health policies**

The Union carried out in 2003, 2006 and 2009, public opinion polls to monitor Europeans' attitudes towards alcoholic beverages.

The general aim of these surveys was to monitor citizens' alcohol consumption patterns, their awareness of the adverse health risks and social effects involved as well as opinions regarding

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<sup>121</sup> [scheer\\_o\\_003\\_0.pdf \(europa.eu\)](#).

<sup>122</sup> Results from the Horizon Europe project "EUonQoL", including use of the EuonQoL-Kit, will be taken into account, as well as the Innovation Action funded under call topic "HORIZON-MISS-2023-CANCER-01-04: Establish best practices and tools to improve the quality of life for childhood cancer patients, survivors and their families".

policy options to reduce alcohol-related harm, in particular concerning health information on the labels of alcoholic beverage products. The fourth Eurobarometer on attitudes towards alcohol consumption should provide updated information on citizens' alcohol consumption patterns such as drinking in terms of prevalence, frequency and the amount that is consumed. Furthermore, citizens' attitudes and behaviour towards drinking, safety and public health shall be examined including their knowledge about alcohol associated health risks, such as cancer. Finally, citizens' support for public policies on alcohol in particular different types of health information on the labels of alcoholic beverages shall be ascertained.

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 (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangements, service, framework contract

Indicative budget for this thematic area: EUR 500 000

Implementation by: DG SANTE

## **3.2 STRATEGIC AGENDA FOR MEDICAL IONISING RADIATION APPLICATIONS**

### **CR-p-23-44-02 To support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – study on the implementation of the EURATOM and the Union legal bases with respect to medical devices used in medical applications of ionising radiation**

A variety of nuclear and radiation technologies play a key role in the fight against cancer. Mammography, computed tomography and other forms of radiological imaging are indispensable technologies for all stages of cancer management. Radiotherapy is among the most effective, efficient and widely used cancer treatments available to patients and physicians. Nuclear medicine is routinely used for cancer diagnosis and follow-up, and increasingly available for cancer treatment.

Medical applications of ionising radiation are constantly evolving in a complex regulatory environment and there is scope to improve coordination in implementing the different regulatory frameworks. This is the case with regard to medical devices used in medical applications of ionizing radiation that are subject to the EU medical devices and the Euratom radiation protection legislations, both setting requirements for installation and acceptance testing, reporting of adverse events, and other indicators. The results of the work will underpin further efforts to improve the coordination between the two legal bases and support their efficient implementation for the benefit of patients.

This action supports the implementation 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 defined in Article 4, points (a) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service

Indicative budget for this thematic area: EUR 300 000

Implementation by: DG SANTE / HaDEA

## **4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)**

### **4.1 REFORMING AND STRENGTHENING THE HEALTH SYSTEMS**

#### **HS-p-23-46 The role of healthcare in reducing poverty**

Improving access to healthcare is one of the priority areas (Principle 16) of the European Pillar of Social Rights (EPSR). The EPSR Action Plan adopted in 2020 aims at reducing the number of people at risk of poverty or social exclusion by at least 15 million by 2030. Healthcare benefits play an important role in mitigating and reducing poverty, but this is currently not measured. The Action Plan includes a commitment to reduce inequalities in access to healthcare and improve metrics of access to healthcare on top of a commitment on

the better use of distributional impact assessment of policies. The EPSR Action Plan also announced that the Commission will prepare guidance to help Member States increasing their use of ex ante distributional impact assessments. The proposed action would therefore directly contribute to the implementation of the EPSR Action Plan.

The report on ‘access to healthcare’ from the Expert Group on Health Systems Performance Assessment, published on 14 April 2021, concludes that the analysis of the impact of in-kind health benefits on poverty reduction can complement the metrics used at EU level and support policy-makers in addressing inequalities in access to healthcare. Health status is closely linked with socio-economic status. Affordability of health services remains a barrier to healthcare, especially for people in lower income groups, which is clearly demonstrated by data on unmet medical needs and catastrophic spending on healthcare. Healthcare coverage, including parameters related to the level of co-payments, deductibles, can play a big role in mitigating and reducing poverty. In-kind health benefits represent 30 percent of total social benefits and their impact on poverty or inequality is not measured at EU level. This is an important policy shortcoming at EU and national levels and the project will aim to address this gap.

The results of the action could be used in the European Semester, including for the budgetary planning, and the assessment of poverty-mitigation health policy reform scenarios. The outcome of this action will be key for evidence-based policy-making as it will inform in a comprehensive manner about the impact of health policies on the incomes of different groups of the population as well as on poverty and income inequalities. It will provide a way to measure which socio-economic groups are gaining and losing from a given health reform in a transparent manner.

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, point (g), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: administrative arrangement with DG JRC

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

## **4.2 ENHANCING EUROPEAN REFERENCE NETWORKS**

### **HS-p-23-48 Business continuity of the IT systems of the European Reference Networks (ERNs): Operation of the current clinical patient management system (CMPS) and development and deployment of the new CPMS**

This action ensures the business continuity for the period 2023-2027 of the IT system of the ERNs that allows for remote medical discussions on rare clinical cases. It addresses the operation and maintenance of the current system and the development and deployment of the

new Open Source system that will facilitate a smoother integration of the ERNs into the health systems of Member States, and pave the way to expand to national networks of rare and even to non-rare diseases. The action also ensures the business continuity of subsidiary the non-clinical IT systems used by the ERNs.

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, points (g) and (i), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: Specific contracts under existing framework contracts

Indicative budget for this thematic area: EUR 6 000 000

Implementation by: DG SANTE

#### **4.3 IMPLEMENTATION OF CROSS-BORDER HEALTHCARE DIRECTIVE**

##### **HS-p-23-47 Enhancing the implementation of the Cross-Border Healthcare Directive 2011/24/EU and improving information to patients**

Commission's evaluation of the Directive 2011/24/EU concludes that awareness of cross-border healthcare remains low, that more efforts are necessary to improve information to patients and that differences in national health systems are a major obstacle to cross-border healthcare, notably in border regions. The Commission's report sets out actions to support Member States and the National Contact Points on cross-border healthcare to improve the implementation of the Directive for the benefit of patients.

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

Indicative type of contracts/supply: framework contract or open call for tenders

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA

#### **4.4 IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND PHARMACEUTICAL STRATEGY FOR EUROPE**

##### **HS-p-23-53 Administrative Support to the National Competent Authorities on Pricing and Reimbursement (NCAPR)**



The Pharmaceutical Strategy for Europe<sup>123</sup> mentions that the Commission will step up co-operation with and among Member States on the affordability and cost-effectiveness of medicines and will launch a group to steer cooperation between national pricing and reimbursement authorities and healthcare payers. This group should support mutual learning through information and best-practice exchange, including on public procurement and the coverage of pharmaceutical costs by social protection systems, price-increase criteria and rational prescribing.

This action aims at keeping up the efficient implementation of the work plan of the group as the work has intensified.

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, point (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: Specific contracts under existing framework contract

Indicative budget for this thematic area: EUR 100 000

Implementation by: HaDEA

### **HS-p-23-55 Member States' participation to the monitoring/audit mutual recognition agreements in the pharmaceutical field**

This action will support the participation of Member States as experts in audits in the fields of active pharmaceutical ingredients, mutual recognition agreements in that pharmaceutical field, and clinical trials. It will also include the participation of auditors in the good manufacturing practice (GMP) and good clinical practice (GCP) joint audit programme in the Union and third countries for the quality of medicines in order to support the international harmonisation of requirements for pharmaceuticals and regulatory convergence.

The action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, (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: service

Indicative budget for this thematic area: EUR 70 000

Implementation by: DG SANTE

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<sup>123</sup> COM (2020) 761 final.

## **HS-p-23-54 Capacity building to support the uptake of biosimilars in a multi-stakeholder approach**

Biological medicines represent an increasing proportion of medicine spending, and the Pharmaceutical Strategy for Europe acknowledges the potential of biosimilars to improve pricing competition. Higher uptake of the latter by Member States can create a savings potential for health systems - not in the least given the upcoming loss of exclusivities in major molecules - and above all improve access and affordability of treatments. However, while some countries have seen significant increases in biosimilar market penetration, others are lagging behind. Therefore, the Pharmaceutical Strategy for Europe sets out that the Commission will continue to work on biosimilar uptake by Member States, including through the exchange of best practices.

The action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, (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: open call for tenders

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: HaDEA

## **HS-p-23-58 Data Analytics**

Developing and implementing digital ready policies is a cross-cutting political priority in Member States and also at EU level. Limited information/data for national decision makers prevents Member States from finding and implementing optimal strategies in healthcare.

Information exchange to promote the affordability of pharmaceuticals is one objective of the Pharmaceutical Strategy for Europe. The interoperability of existing digital solution is also key to more efficient European collaboration including coherence across sectors. There are a number of important investments in Digital Europe; these should also be leveraged for optimal data analytics including solutions based on artificial intelligence.

The action supports the implementation of EU 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: administrative arrangement

Indicative budget for this thematic area: EUR 150 000

Implementation by: DG SANTE

## **HS-p-23-59 IT support to the European Medicinal Products database ('EMP')**

The purpose of 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 (EMA). 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 objective defined in Article 4, point (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

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

#### **HS-p-23-63 Support to the technical secretariat for Notified Bodies Coordination Group**

To secure smooth implementation of sectorial legislation, the Commission provides support to the activities of Notified Bodies established under different sectorial Legislation (e.g. Machinery Directive 2006/42/EC; EMC Directive 2014/30/EU). Notified bodies are facing some challenges in the implementation of the newly established Medical Device Framework and such support is essential to contribute to a smoother implementation of Regulations (EU) 2017/745/EU<sup>124</sup> and 2017/746/EC of the European Parliament and of the Council<sup>125</sup>.

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,

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<sup>124</sup> 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).

<sup>125</sup> 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).

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: framework contract or open call for tenders

Indicative budget for this thematic area: EUR 200 000

Implementation by: HaDEA

### **HS-p-23-67 Technical and administrative support to the medical device coordination group (MDCG)**

The Medical Device Coordination Group (MDCG) is a Group of Member States representatives, instrumental to support the implementation of the Medical Devices Regulations. The MDCG has 13 Working Groups dealing with specific parts of the Medical devices Regulations. The action would provide administrative and technical support to the MDCG in organising, preparing and following up the regular meetings of the MDCG and its main working groups.

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: service contract

Indicative budget for this thematic area: EUR 250 000

Implementation by: HaDEA

### **HS-p-23-68 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 300 000

Implementation by: DG SANTE

## **HS-p-23-69 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. This action will support the finalisation of development, improvement and maintenance of the EUDAMED database. EUDAMED is one of the core elements of MDR and IVDR. Its use by economic operators, competent authorities 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 2023 is supporting the last and most critical phase of its development.

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

Indicative budget for this thematic area: EUR 6 000 000

Implementation by: DG SANTE

## **4.6 IMPLEMENTATION OF REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT**

### **HS-p-23-60 Ensuring the development and completion of the IT platform**

This action concerns the preparation phase leading to the implementation of Regulation (EU) 2021/2282 on Health Technology Assessment (HTAR), in particular to secure the development and maintenance of the necessary IT platform to perform joint work as provided by Regulation (EU) 2021/2282 on Health Technology Assessment (Articles 28 (f) and 30).

This action supports the implementation of the HTA Regulation and implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d) 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: administrative arrangements

Indicative budget for this thematic area: EUR 2 000 000

Implementation by: DG SANTE

## **HS-p-23-61 Building capacity and knowledge in preparation of the implementation of HTA Regulation**

Regulation (EU) 2021/2282 will be implemented from January 2025. Taking into account the high interest expressed by participating HTA bodies to consolidate their knowledge and experience on joint HTA work before the implementation date, this action aims to provide training to national assessors and HTA national authorities on the guidelines and the procedures developed by the HTA Coordination Group, based on relevant the technical input and on the requirements of the HTA Regulation.

The action responds to the requests from HTA bodies to consolidate their knowledge on joint HTA activities before the implementation of Regulation (EU) 2021/2282.

This action supports the implementation of Regulation (EU) 2021/2282 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 (h) and (i), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service contract

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

### **4.7 GLOBAL HEALTH**

## **HS-p-23-71-02 Operationalise methodology for mapping Union health policy actions and financing streams and develop metrics to assess implementation of the global health strategy**

As an essential part of the Global Health Strategy, the Union will integrate global health considerations into policy-making across all those sectors in a structured fashion. For this purpose, in 2023 the Commission will formalise an internal coordination mechanism within the EU institutions and bodies. All policies, actions and financial streams will be regularly mapped, and coordinated, ensuring they help to deliver on this strategy's priorities. New initiatives will be assessed to ensure they do not undermine global health policy priorities, and be asked wherever possible to contribute to them. Metrics will be developed to help monitor the implementation of the strategy.

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

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

Indicative budget for this thematic area: EUR 300 000

Implementation by: HaDEA

## 5. DIGITAL (DI)

### DI-p-23-74 Operations of MyHealth@EU core services

The cross-border infrastructure MyHealth@EU offers health data sharing services to patients with the aim of ensuring the continuity of care for people/individuals while they are travelling within the EU. Such infrastructure provides the possibility for Member States to exchange health data in a secure, efficient and interoperable way. As a result, MyHealth@EU services enable people/individuals in the Union to benefit from healthcare in the country of travel in the same way that they benefit in the country of residence – via a new digital communication channel.

At present, MyHealth@EU has been progressively rolled-out in 10 Member States on a voluntary basis, and more are in the process of on boarding. Most Member States are expected to participate in MyHealth@EU by 2025. Two services are currently operational: ePrescriptions and Patient Summaries. Both services aim to convey and translate the respective information they contain into the language applicable in the country of travel. Expansion of MyHealth@EU to new services (such as laboratory results and reports, medical images and reports, and hospital discharge reports) is also planned in the coming years. Interoperability can be based on standards such as the ones developed through the MyHealth@EU central terminology services.

On 3 May 2022, the Commission adopted a legislative proposal on the European Health Data Space (EHDS)<sup>126</sup>. According to this proposal, the deployment of the cross-border infrastructure MyHealth@EU would become mandatory for all Member States, with a staged approach for the different categories of health data.

The action prepares the implementation of the proposed EHDS and the cross-border use of health data for the provision of healthcare by ensuring the operation of MyHealth@EU. The action constitutes work conducted every year to support the continuity of operational MyHealth@EU services. The action includes checking the compliance of Member States' national contact points for eHealth with the requirements of MyHealth@EU.

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.

Indicative type of contracts/supply: service, administrative arrangements, co-delegation to DIGIT, and existing or new framework contracts.

Indicative budget for this thematic area: EUR 5 000 000

Implementation by: DG SANTE / HaDEA

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<sup>126</sup> [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en).

## **DI-p-23-76 Enhance MyHealth@EU core services with scenarios supporting patients' access to their health data, taking into account the developments in the context of EU Digital COVID Certificate**

As performed currently, patient identification in MyHealth@EU suffers from some shortcomings. Health professionals need to enter manually patients' identification data and document identifiers. This is burdensome and error-prone (person or document identifiers are commonly over 10-digit long). Additionally, there is no electronic notification to or request for confirmation by the patient when their data is accessed.

In particular, in the current ePrescription services in MyHealth@EU person's identification data needs to be entered manually by a pharmacist. To avoid manual entry of data and to improve security, several Member States have introduced the use of barcodes in their national ePrescription systems. In these national implementations, the barcodes are printed on paper or shown through mobile apps. The barcodes of different Member States are not however interoperable and therefore not used in MyHealth@EU, resulting on situations where barcodes issued by one Member States are not understood by a pharmacy system in another Member State.

In many Member States people can directly access (without the need for a health professional mediation) to their Patient Summaries or parts thereof, such as vaccination data. Individuals can share the data with a health professional in another Member State by showing the data on their mobile phone, however, they are unable to prove the authenticity of this data. The current MyHealth@EU services always rely on the initiation of access to data by health professionals and do not enable citizens to directly share their health data with people and organisations of their choice (e.g. health professionals not connected to MyHealth@EU) or to prove the authenticity of the data (e.g. a vaccination certificate). Only health professionals in organisations connected to MyHealth@EU can access these health information services. However, the need for people to be able to share their health data is broader, and technologies for this are being currently designed G7, G20 and the WHO, based on digital health trust networks.

As shown by the EU Digital COVID Certificate (EU DCC) implementation, today's widespread use of smartphones and QR code technology can be used to overcome most of the limitations described before. The know-how and solutions acquired with the implementation of the EU DCC should be adjusted and put to use to enhance MyHealth@EU services and functionalities. In particular, the use of the EU DCC technology in connection with MyHealth@EU services would be fundamental for the development of interoperable vaccination card functionalities by Member States.

Therefore, there is a need to extend the central services of MyHealth@EU to enable scenarios based on the use of smartphones, including QR code technology, taking into account the examples developed in the context of the EU DCC.

This procurement complements action DI-g-23-77 on "direct grants to Member States' authorities: development and enhancement of MyHealth@EU services, including vaccination card services". This action (DI-p-23-76) covers the development and deployment activities needed at the level of the central services, i.e. those provided by the European Commission.



Action DI-g-23-77 covers the development and deployment of new services to support patients' access, on the basis of the EU DCC technology framework, at the level of the national contact points for eHealth, which is at the level of the generic services. Both are needed for the cross-border services to function in the MyHealth@EU infrastructure.

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, points (f) of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service, administrative arrangements, co-delegation to DIGIT and existing or new framework contracts.

Indicative budget for this thematic area: EUR 2 000 000

Implementation by: DG SANTE

### **DI-p-23-78 Database for Electronic Health Record (EHR) systems and wellness applications compliant with the proposed EHDS requirements**

On 3 May 2022, the Commission adopted a legislative proposal on the European Health Data Space (EHDS). This legislative proposal aims not only at empowering people to access and control their health data but also at streamlining data access for their reuse in the context of activities that will benefit society. To foster the interoperability of digital health software, the EHDS proposal also introduces the mandatory certification of Electronic Health Record systems (EHR systems). Such certification relies on interoperability and security requirements to be met by EHR systems as well as devices interacting with EHR systems. In addition, a voluntary labelling scheme is introduced for wellness applications and based on similar interoperability and security requirements.

In the context of the mandatory certification of EHR systems, manufacturers are requested to comply with different obligations, from the drawing up of a technical documentation, information sheet, EU declaration of conformity and CE marking to the involvement in market surveillance activities. In addition, one of the obligations of the manufacturers is to register their EHR systems in an EU database established and maintained by the Commission.

According to the EHDS proposal, manufacturers of wellness applications that are interoperable with EHR systems will be able to issue a label that will accompany the wellness application. With this label, users will be informed of wellness applications' compliance with interoperability and security requirements similar to the ones defined for EHR systems.

This action aims to establish a publicly available database with information on EHR systems and wellness applications. This EU database will not only provide transparency for procurers on the EHR systems which are available on the market and for users on wellness applications which are labelled but also support market surveillance authorities in the context of their activities. Whenever applicable and possible. For the development of this database, the reuse and extension of the EUDAMED database established under the Medical Device Regulation will be considered whenever applicable and possible.

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, points (f) of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service, administrative arrangements, co-delegation to DIGIT and existing or new framework contracts.

Indicative budget for this thematic area: EUR 3 100 000

Implementation by: DG SANTE

### **DI-p-23-80 Development, deployment and operations of the core services of the infrastructure on secondary uses of health data (HealthData@EU)**

In the context of European Health Data Space, researchers, companies or institutions will be able to access health data by applying for a permit from one of the health data access bodies, which should be set up in all Member States. In the proposed Regulation, a new decentralised EU-infrastructure for secondary uses of health data (HealthData@EU) will be set up, supporting cross-border health data access, connecting health data access bodies, authorised international health data research infrastructures and relevant EU bodies.

This new infrastructure (HealthData@EU) should also minimise the transfer of data (e.g. bringing the queries to the data instead of transferring the data). Following the model of MyHealth@EU from the context of primary use, the Commission will be responsible for the common services in the federation. Health data access bodies, authorised international health data research infrastructures and EU bodies participating in this EU-wide infrastructure will be responsible for the nodes in the federated infrastructure.

A pilot to develop the HealthData@EU infrastructure is planned to be launched in 2022. This is only a first step. Therefore, there is a need to support further the development, deployment and operations of the infrastructure, and to prepare its EU-wide scale-up, both in the context of the pilot and beyond it. The objective of this action is to provide such support and to accelerate preparations on the Commission's side to provide the necessary services ahead of the large-scale deployment.

This action implements the EU4Health Programme 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), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service, administrative arrangements, co-delegation to DIGIT and existing or new framework contracts.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: DG SANTE

## **DI-p-23-81 Capacity building for secondary uses of health data for the European Health Data Space**

The landscape of secondary uses of health data in the Union is characterised by fragmented and divergent legal and administrative rules, frameworks, processes, standards and infrastructure. There are significant differences between Member States in the capacity and preparation to deal with secondary uses of health data in the context of the proposed EHDS. Some Member States have established health data access bodies, responsible for granting access to electronic health data for secondary use, while others are starting the preparation but lack the necessary knowledge, expertise or skillset.

To overcome this, there is a need to support the transfer of knowledge and exchange of best practices among more advanced Member States and Member States willing to invest in this area. This action will build on the work of the joint action “Towards a European Health Data Space” (TEHDS), and other initiatives, and use the twinning approach to develop the exchange of best 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 objectives defined in Article 4, points (f) of Regulation (EU) 2021/522.

Indicative type of contracts/supply: service

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: HaDEA

In the context of the Digital strand the Commission may launch a call for establishing a framework contract on trans-European and/or integrated systems for the management of digital health policy processes, information and data. The framework contract may cover thematic areas such as (i) IT consultancy services (analysis, studies, benchmarking, architecture and design), (ii) proof of concept, prototypes and pilots, (iii) IT development and operations in the field of information systems, and (iv) managed services and support.

Additionally, the Commission may launch a call for establishing a framework contract on trainings and capacity building programmes in health, including digital health.

## **6. RECURRENT, HORIZONTAL, IT AND COMMUNICATION ACTIVITIES**

The actions have as objectives the organisation of events in the field of health and global health, the logistical support and technical assistance 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) in the field of risk

assessment and research, the enhancement of the Health Policy Platform, the support to Steering Group on Health Promotion, Disease Prevention and Management of non-communicable diseases (SGPP), its subgroups and other groups, the support in studies, analysis, impact assessments and evaluations of health-related legislation.

Furthermore, the objectives are to communicate on the EU4Health Programme and the EU priorities it supports, on actions supported by the programme, and to ensure the necessary technical expertise for horizontal activities such as graphic design or website management and maintenance.

In line with the Commission's ambition to build a European Health Union for people and the Commission's One Health approach, communication in 2023 will focus on key political priorities including the Health Union, Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, vaccination, AMR and Global Health Strategy.

Moreover, in accordance with Article 26 (3) of Regulation (EU) 2021/522 and as announced in the Communication to the Commission on 'Corporate Communication action in 2021-2023 under the Multi-annual Financial Framework 2021-2027', the corporate communication of the Union's political priorities to the extent that they are related to the objectives referred to in Articles 3 and 4 Regulation (EU) 2021/522 will be supported.

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

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.

This action also covers supporting legal service for HERA, the organisation of matchmaking events of the Joint Industrial Cooperation Forum, the experts evaluation for proposals received by HaDEA and DG SANTE, studies on the COVID-19 pandemic, studies and experts and technical support for the implementation of Regulations (EU) 2017/745 and 2017/746 and other Union legislations on health, studies to identify future challenges and priorities in health and food safety. This action also supports the implementation of the Council recommendation 2018<sup>127</sup> related to the report on the state of vaccine' confidence in the Union to monitor attitudes on vaccination.

The expected results are:

**for activities of SGPP and Health Policy Platform (HPP):** management of expert groups, assessments of proposals for best and promising practices, maintenance of the platform, organising HPP annual meeting;

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<sup>127</sup> 2018/C 466/01.

**for activities of scientific committees, functioning of expert groups, meeting 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;

**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;

**for vaccination confidence:** a service contract to measure the confidence on vaccination of general population and health professionals, about quality and safety of vaccines, with reports by general population and health professionals, and individual country fiches;

**for IT:** provision of corporate technical services;

**for evaluation:** e.g. mid-term evaluation of the EU4Health programme; the evaluation of Regulation on serious cross border threats to health<sup>128</sup> and the evaluation of Regulation on an extended mandate of the European Centre for disease prevention and control<sup>129</sup>;

**for legal support:** framework contract to be launched;

**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.

Within this thematic area, the Commission plans to launch open procedures for a framework contract for the provision of legal support.

Indicative type of contracts/supply: service, open procedures or competitive procedures with negotiation or competitive dialogue procedure, administrative arrangements, co-delegation with DG COMM, co-delegation with DG DIGIT.

Indicative budget for this thematic area: EUR 13 258 071

Implementation by: DG SANTE / HaDEA

## C. OTHER ACTIVITIES

In 2023, the Commission intends to launch the following other actions which contribute to one or several strands.

### **DP-o-23-37 SUPPORT FOR EUROPEAN CLIMATE AND HEALTH OBSERVATORY**

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<sup>128</sup> COM(2020)727 final.

<sup>129</sup> COM(2020)726 final.

The actions under this thematic section have as objective to provide support for the development of a governance model and rules for the sharing of public health data for secondary use and for the development, deployment and operation of an IT system and data tool that will enable access to health data for secondary use, i.e. for research and development, policy-making and regulatory activities. Furthermore, and embracing the One Health approach, the further development and implementation of the work plan 2021/2022 of the European Climate and Health Observatory aims at supporting adaptation plans and measures in Member States related to climate change and health.

This action will contribute to daily operation and the further development of the European Climate and Health Observatory work.

Indicative type of contracts/supply: Service Agreement

Indicative budget for this thematic area: EUR 400 000

Implementation by: DG SANTE

### **CP-o-23-64 SUPPORT FOR THE DIGITAL PASSENGER LOCATOR FORM (EUdPLF) PLATFORM**

This action will aim to support the continuation of the operations of the EU digital passenger locator form (EUdPLF) platform in a stand-by mode. This tool is part of the EU preparedness and response measures and should be maintained at a minimum level so that it could be activated in case of reemergence of a new COVID-19 strain with higher pathogenicity or other communicable diseases causing epidemics, such as influenza pandemic strains.

In the EUdPLF standby mode operation, the Member States that use the EUdPLF platform will suspend the collection of PLF data. In case the epidemiological situation would demand collection of travellers' data to support cross-border contact tracing, the participating countries will be able to reactivate their national PLF operations quickly via the EUdPLF.

The EUdPLF in stand-by mode would be limited to the following services: a) basic operations center, b) hosting and maintenance of the EUdPLF application and website and c) third-party services (ticketing system airline and airport directory, railway directory and flights Advance Passenger Information (API)). Member States will provide other services themselves like a traveller's helpdesk and online training services.

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

Indicative type of contract/supply: Service Contract

Indicative budget for this thematic area: EUR 300 000

Implementation by: HaDEA

## **MEMBERSHIP FEES TO INTERNATIONAL ORGANISATIONS AND REGULATORY BODIES**

**HS-o-23-56-01 Annual membership fee to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)<sup>130</sup> and participation of experts from Member States in ICH meetings**

**HS-o-23-56-02 Annual contribution to the International Pharmaceutical Regulators Programme<sup>131</sup> (IPRP)**

This action covers the contribution to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ('ICH') and to the International Pharmaceutical Regulators Programme (IPRP) of which the Commission is a founding member. It also supports the participation of experts from Member States in ICH meetings with the objective to participate in the harmonisation of technical requirements, including scientific aspects, of medicinal product registration at international level.

Indicative budget: EUR 700 000

Implementation by: DG SANTE

**HS-o-23-72 Annual contribution to the European Observatory on Health Systems and Policies<sup>132</sup>**

This action covers the contribution to the European Observatory on Health Systems and Policies to which the Commission is a participating organisation. It supports and promotes evidence-informed policy-making decisions on European health systems.

Indicative budget: EUR 700 000

Implementation by: DG SANTE

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<sup>130</sup> Commission Decision of 23 October 2015 on the participation of the Commission as Founding Regulatory Member in the 'International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use', C(2015)7256 final.

<sup>131</sup> Commission Decision of 18 May 2021 on the participation of the Commission as a Member in the 'International Pharmaceutical Regulators Programme', C(2021) 3312 final.

<sup>132</sup> Commission Decision of 21 December 2009 on its incorporation as a Participating Organisation of the 'European Observatory on Health Care Systems and Policies' project, C(2009)10213 final.

## **D. ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT**

### **ACTIONS WITH A COST OF EUR 20 000 000 OR MORE**

#### **CP- CO-23-09 Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the InvestEU Fund (HERA)<sup>133</sup>**

##### **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”<sup>134</sup> 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 (MCM). There is a need to combine public and private efforts to incentivise 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.

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 objectives 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 InvestEU Fund. The budgetary amount will be EUR 100 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, and diagnostics, as mentioned in the guarantee agreement between the EIB and the Commission. The funds will be managed by DG ECFIN via co-delegation type II. The implementing entity is the EIB. HERA will cooperate with EIB for the successful implementation of the action.

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<sup>133</sup> This blending operation is referred to as “HERA INVEST”.

<sup>134</sup> [Communication on the early lessons from the COVID-19 pandemic \(europa.eu\)](https://ec.europa.eu/health/communication_early_lessons_from_the_covid-19_pandemic_en).



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 investment, and contributing to the R&D pipeline of MCMs against 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 CEPI<sup>135</sup> or the novel WHO/World Bank financial intermediary fund focus or will focus either on the development of only one class of MCMs, or do not sufficiently fund end-to-end (early research to market) development of MCMs. Moreover, their focus is international. Their investments do not always guarantee the EU 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 MCMs.

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 into MCMs can be mitigated, investments will focus on projects targeting the development of preventative, treatment or diagnostics MCMs 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 fund.

#### **EXPECTED RESULTS AND IMPACT**

This action can effectively incentivise private investment by leveraging public funds. A top-up of EUR 100 million (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 InvestEU 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 HERA action promotes innovation and development of new MCMs and will create positive spill overs for international partners.

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<sup>135</sup> [CEPI | New Vaccines For A Safer World.](#)

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
CP-CO-23-09	Q1-Q3/2023	EUR 100 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Implementing Entity</b>
Indirect management	Co-delegation type II to DG ECFIN	EIB

**ACTIONS WITH A COST BELOW EUR 20 000 000****CP-CA-23-25 Support to improve intelligence gathering, including clinical trials in Africa - Strengthening Health Emergency Preparedness and Response (HERA)****POLICY CONTEXT**

HERA will contribute to the development, manufacturing, procurement and distribution of key medical countermeasures within the Union so as to be better prepared for and respond to serious cross-border threats and emergencies – whether of natural or deliberate origin. HERA’s mission is to work to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, among others by contributing to reinforcing the global health emergency preparedness and response architecture.

Emerging serious cross-border health threats have a global nature and therefore need to be looked with a global perspective. A stronger health architecture is needed considering the global nature of health threats, the global dynamics of medical countermeasures development and deployment and the need for stronger surveillance and cooperation for health emergency detection, response and recovery. This includes analysing data on potential outbreaks as well as rapid and transparent cross-sectoral and international information and data sharing. The WHO pursues a collaborative intelligence with the aim to enable the generation of public health relevant information, reduce fragmentation and inefficiency by promoting collaboration and enhance informed public health decision-making.

Many countries in Africa are developing their capacities to detect and monitor outbreaks and other cross-border health threats, however, capacities to optimally manage and analyse data continue to be limited in the region. The proposed activities will contribute to the intelligence

gathering and threat assessment functions of HERA for medical countermeasures, while specifically addressing the threat of emerging infections on the African continent. By linking the HERA – WHO Pandemic Hub partnership with the existing WHO AFRO - Africa CDC collaborations to strengthen the health intelligence architecture, this project will enable partners and Member States to better prepare and respond to cross border health threats and emergencies – whether natural or deliberate in origin. The action will be coordinated in synergy with other relevant activities, such as the Team Europe initiatives (TEIs) with Africa regarding health security using a One Health approach or the TEI on digital health in Africa.

In addition, late-stage clinical trials under WHO sponsorship in Africa will be supported, testing the efficacy of novel treatments and/or vaccines for high-priority threats (e.g. ongoing Sudan ebola virus outbreak) where no authorised medicines are available. Integration of clinical trials in the outbreak responses in Africa will allow the evaluation of potentially efficacious candidate medicinal countermeasures and potentially contribute to better prepare and respond to outbreaks. Following a regulatory authorisation, these safe and efficacious medicines could protect populations at risk in the EU (including in case of imported cases or amongst health-care workers deployed to Africa) as well as globally (including in Africa in case of future outbreaks) in the future.

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 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.

The action supports the EU’s global commitments and health initiatives and 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) 2021/522) through the specific objectives defined in Article 4, points (b), (c) and (j), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objectives of this action are to:

- a) improve public health emergency preparedness and response architecture across Sub-Saharan Africa and globally by supporting data and information management strengthening activities of the Transforming African Surveillance Systems (TASS) Flagship Project;
- b) contribute to the conduct of late stage clinical trials in Africa under WHO sponsorship to evaluate vaccines and/or treatments for high priority health threats (e.g. ebola virus) toward regulatory submission;
- c) support information system architecture design for existing and new information systems across Africa to achieve interoperability across the region and internationally;

- d) establish working links global centres of expertise for data science and data analytics;
- e) conduct training and capacity building activities with African institutions.

#### **EXPECTED RESULTS AND IMPACT**

This action is expected to contribute to strengthening the global capacities to prevent, prepare and respond to cross border health threats, resulting in enhancing preparedness and response at EU level by providing information, capacities, and tools to generate the biggest possible impact to prevent, prepare and allow adequate response to cross border health threats.

Contribution to global initiatives will improve coordination, communication and community engagement, therefore improving detection and coordinated response to health emergencies. This action will thus facilitate and improve the exchange of data across borders in relation to cross-border health threats and relevant medical countermeasures. It will also contribute to the development and increased availability of safe and efficacious novel medicines to prevent or address ongoing and future outbreaks.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
CP-CA-23-25	Q1-Q2/2023	EUR 7 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	HERA/HaDEA <sup>136</sup>	WHO

<sup>136</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

## **CP-CA-23-06 European Immunization Agenda (EIA2030) monitoring and accountability framework for high quality data towards evidence-informed decision-making**

### **POLICY CONTEXT**

The implementation of the WHO European Vaccine Action Plan (EVAP 2015-2020) had many successes such as sustained polio-free status in the Region, increased number of Member States verified as having eliminated measles and rubella, progress with documenting hepatitis B control, improved evidence-based introduction of new/underutilized vaccine. The strong foundation of immunisation programmes enabled also an effective roll-out of COVID-19 vaccine as response to unprecedented pandemic, reaching 50% uptake of the whole population in the WHO European region, within 8 months since the beginning of COVID-19 vaccination campaign. However, not all the EVAP targets have been met. There is a real risk that complacency will undermine past achievements. In addition, the COVID-19 pandemic strained routine immunisation programmes and has put at risk the gains achieved, thus far.

Evidence-informed decision-making based on a functional immunisation information system and a robust national and subnational monitoring and evaluation framework, including an accountability mechanism, will lead to an improvement in the quality of overall delivery of the immunisation programmes and will facilitate identification of subnational areas of suboptimal vaccination performance, guide identification of the reasons and plan for tailored intervention to improve the vaccination coverage.

The European Immunisation Agenda (EIA2030) is one of the flagship initiatives of the WHO European Programme of Work 2020-2025. It aims to achieve the full benefits of immunisation in the WHO European Region for the next decade and builds on the achievements and lessons learned from implementation of the EVAP 2015-2020. The EIA 2030 has a focus on the inclusion of vulnerable populations in the national immunisation plans to ensure that every population group in every country is protected from vaccine-preventable diseases. For the period 2020-2030, the Commission issued a reinforced and reformed EU strategic framework<sup>137</sup> for Roma populations in Europe, including initiatives to increase the access to healthcare and vaccination for these groups.

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 body with the required expertise and capacity to implement this action.

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<sup>137</sup> [https://ec.europa.eu/info/policies/justice-and-fundamental-rights/combating-discrimination/roma-eu/roma-equality-inclusion-and-participation-eu\\_en](https://ec.europa.eu/info/policies/justice-and-fundamental-rights/combating-discrimination/roma-eu/roma-equality-inclusion-and-participation-eu_en).

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 of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (b), (c) and (j), of Regulation (EU) 2021/522.

### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objective of this contribution agreement is to promote evidence-based decision-making to monitor progress towards EIA2030 and corresponding relevant EU strategies/plans.

The establishment and functioning of the EIA2030 monitoring and assessment framework for Member States and other countries associated and participating to the EU4Health Programme will contribute to and complement the relevant immunisation reporting mechanisms of the ECDC, at the same time informing countries of their performance in achieving the set IA2030 goals that the Union is engaged towards.

Planned activities include:

- a) monitoring the progress towards EIA2030 goals and targets by countries participating in the EU4Health programme of the WHO European Region;
- b) leverage of the EIA2030 monitoring and assessment framework at national and subnational level to identify and tackle inequitable access to the immunisation programme and health threats related to vaccine preventable diseases.

The activities above should also include a focus on increased uptake of vaccination among Roma populations.

### **EXPECTED RESULTS AND IMPACTS**

This action is expected to ensure that Member States and other countries that participate and are associated to the EU4Health Programme are aligned with the WHO EIA2030 and achieve their goals.

It is in line with the Council Recommendation on strengthened cooperation against vaccine-preventable diseases (2018) which aims at:

- a) a decrease in vaccinated and under-vaccinated population in subnational levels in the countries thereby preventing outbreaks of the vaccine-preventable diseases;
- b) an increase in vaccination coverage of routine vaccines in the national immunisation schedule leading to decrease in morbidity and mortality;
- c) strengthened regional health security from infectious diseases and reduction of cross-border health threats.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CP-CA-23-06	Q3-Q4/2023	EUR 2 000 000
Procedure type	Implemented by	Entity
Indirect management	SANTE/HaDEA <sup>138</sup>	WHO

### **CP-CA-23-07 Risk assessments for chemical, environmental and climate threats drawn up within agencies (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU<sup>139</sup>)**

#### **POLICY CONTEXT**

A rapid response to cross-border threats to health requires surveillance and monitoring mechanisms to ensure timely detection and identification of threats to health. Early lessons learnt from the COVID-19 pandemic have shown that the EU's preparedness and response to cross-border threats to health were sub-optimal.

Besides threats of biological origin, such as communicable diseases and antimicrobial resistance and healthcare-associated infections related to communicable diseases, the following categories of serious threats to health events have been identified:

- a) biotoxins or other harmful biological agents not related to communicable diseases;
- b) threats of chemical origin;
- c) threats of environmental or climate origin;
- d) threats of unknown origin.

Timely surveillance, integrated with other areas, and a robust early warning and response system (EWRS) covering the reporting of all hazards, is therefore essential to ensure a timely identification of agents with epidemic potential and response to health emergencies. The funds would be activated to carry out activities such as public health risk assessment, in case of an alert, a serious cross-border threats that represents an EU public health emergency situation.

In accordance with Article 7(1) and Article 13(1) point (b) of Regulation (EU) 2021/522 EFSA, ECHA, EEA, EMCDDA, EUROPOL, EMA are the eligible legal entities to implement this action. They play a crucial role in strengthening cooperation among the Union

<sup>138</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

<sup>139</sup> 2020/0322 (COD), not yet published in the Official Journal.

and Member States actors in conducting risk assessments 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 action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a), (b) and (c), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

Where an alert is notified in EWRS, the Commission will, where necessary, coordinate the response at EU level or upon request of the Health Security Committee.

Depending on the origin of the threat to health, one or more of the following agencies European Food Safety Authority (EFSA), European Chemical Agency (ECHA), European Environment Agency (EEA), European Centre for monitoring Centre for Drugs and Drug Addictions (EMCDDA), European Medicines Agency (EMA), will be called in to promptly carry out public health risk assessments. In turn, the Commission can promptly make available the risk assessment of the potential severity of the threat to public health, including possible public health measures: to the national competent authorities and to the Health Security Committee through the EWRS. If the threat is emanating from man-made intentional release, the relevant agency will carry out the assessment with the European Police Office (Europol). Other EU agencies could be invited to contribute when the events occur in occupational settings.

#### **EXPECTED RESULTS AND IMPACT**

Promptly carrying out and delivering public health risk assessments, including possible public health measures.



**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
CP-CA-23-07	Q2-Q3/2023	EUR 600 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>140</sup>	EFSA, ECHA, EEA, EMCDDA, EUROPOL, EMA

**CP-CA-23-03 Improving and strengthening the EU early warning and response system and national alert and information systems (EWRS) (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU<sup>141</sup>)**

**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.

The EWRS will enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

The 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.

EWRS will be set-up for addressing a wide range of threats, including biological chemical and environmental threats to health as well as threats of unknown origin.

This action aims to upgrade the EWRS system to allow the system to adapt to the new requirements covering a wider range of threats by linking the national competent authorities for the reporting of all health threats to EWRS and by integrating to the existing other EU alert and information system (AIS).

<sup>140</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

<sup>141</sup> 2020/0322 (COD), not yet published in the Official Journal.

In addition, EWRS will need to develop new functionalities and modules to support the public health risk assessments, the Union and national preparedness and response plans (article 6) and the reporting on preparedness and response planning and support to crisis management.

To align with the new Regulation, the EWRS data security and data protection will be improved, by taking into account the results and recommendations of a recent study under the 2021 annual work programme, 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.

It is therefore vital to consider exactly how EWRS can 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.

This action will build on the results of the EWRS future developments assessment contract, which is a preparatory action, under development. This service funded under the AWP 2021, under the BEACON DIGIT/2020/OP/0005 FWC, aims to perform the assessment and proof of concepts of the EWRS platform future developments. This will include the review of the legal, institutional, and alert-information system landscape EWRS operates in, the information sources and analytical methods employed, and an opportunity to envision a new and expanded governance, architecture, and capabilities required to effectively support EU health security decision making and response. In addition, due to the new EWRS use in the MEDEVAC operations and the diversification of EWRS users, there is a need to reinforce the EWRS data security measures.

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, 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 policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a), (b) and (c), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The intended activities to scale-up EWRS, for current and envisaged capabilities, which support the relevant procedures and structures for cooperation on EU level health threats, are described below. These activities are based on the COVID-19 lessons learnt report and the results of the BEACON contract needs assessment (DIGIT/2020/OP/0005): The purpose of these activities is for EWRS to facilitate and support the solidarity, responsibility, and common efforts at EU level that are required to tackle future public health threats.

## **1. Strengthen preparedness and response planning**

- a) 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.
- b) Consultative workshops with country representatives to guide the implementation of new modules for preparedness planning and reporting, including support for a streamlined approach with regards to WHO, International Health Regulation (IHR), State Parties Self-Assessment and Annual report (SPAR). The aim is to ensure common working arrangements which facilitate sharing and use of national preparedness plans and related sensitive information, such as hospital bed availability, intensive care capacity, number of medically trained staff, and other data relevant for managing cross-border threats to health, for efficient collaboration and coordination at both strategic and operational levels.
- c) Support for 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.

## **2. Strengthen security**

- a) Implement the recommendations of the data security audit and data protection impact assessment to further improve data protection and security at EU and national level.
- b) 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 EU institutions and Member States/EAA countries.

## **3. Further progress EWRS towards an ‘all threats’ approach**

- a) Implement a new architecture, making efficient use of new technological developments, information sources, and analytical methods.
- b) Establish an institutional and technical framework for cooperation and automatic information exchange with EWRS, based on identified alert-and information system stakeholders and users.
- c) Integration of other alert and information system to EWRS, by creating a mechanism of pulling alerts from other AIS to EWRS, establishing the connection to EU AIS platforms, including EpiPulse.
- d) Establish procedures and tools for validating the other AIS notifications that fulfil the criteria of a serious cross-border threat to health.
- e) Extending 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.

#### **4. Develop and implement new modules to further support inter-sectorial communication and collaboration.**

- a) Risk Assessment module that can support definition and execution of procedures for requesting, initiating, collaborating, finalizing, and distributing inter-sectorial risk assessments.
- b) 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.
- c) 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.
- d) Action or emergency coordination module to support the Advisory committee exchange of information and coordination of public health crisis.

#### **5. Develop and implement capacity-building actions on the use of the EWRS in Member States and Commission services.**

- a) 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.
- b) 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.

#### **6. Streamline the EWRS procedures and services**

- a) To increase efficiency and coordination between stakeholders using the platform and managing the system at EU and national level.
- b) 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) 216/679<sup>142</sup>.
- c) Develop the user support services with streamlined working arrangements for common and distinct services between helpdesks.

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<sup>142</sup> Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

- d) 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.

#### **7. Support the national crisis management capacities**

- a) Reinforce and develop the national crisis management systems, addressing all hazard threats.
- b) Promote the interoperability, inter-sectorial and inter-regional collaboration in crisis response by developing capacity building and simulation exercises.

#### **EXPECTED RESULTS AND IMPACTS**

The expected results and impact will be:

- a) reinforcement of the existing Early Warning and Response System (EWRS) for all hazards, including chemical, biological, radio nuclear threats to health (CBRN) by linking with the other EU 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 based on the COVID-19 Lessons learnt survey report and to new requirements of the Health Union Regulation, 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, risk assessment, risk communication.
- e) establishment of a training programme adapted to the EWRS capacity building needs related to the use of the EU EWRS platform and adapted to the new EWRS functions and roles.
- f) simplification of the procedures and services to increase efficiency and coordination between stakeholders using and EC and ECDC management of the EWRS system.
- g) reinforcement of the EWRS data protection and data security of the EWRS system function
- h) strengthening the national crisis management system to face all threats.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CP-CA-23-03	Q2-Q3/2023	EUR 2 000 000
Procedure type	Implemented by	Entity
Indirect management	SANTE/HaDEA <sup>143</sup>	ECDC

### **CP-CA-23-04 Ensuring public-health and crisis-response capacities in Ukraine and neighbouring countries (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU<sup>144</sup>)**

#### **POLICY CONTEXT**

There is an urgent need to reinforce Ukraine and neighbouring countries' / countries' participating in the EU4Health Programme, prevention, preparedness and response capacities to chemical, biological and radio-nuclear (CBRN) threats and the health system capacities to address mass war casualties, related to trauma and possible related CBRN events.

The Russian war of aggression against Ukraine and in particular the occupation of the Zaporizhzhia nuclear power plant represent a major threats with the risk of chemical and/or nuclear accidents, due to the dysfunction of the safety procedures. There are many chemical and nuclear facilities in Ukraine, which could face similar attacks and occupation, if the war continues.

Several outbreaks of communicable diseases are occurring in Ukraine, related to the sanitary conditions, disruption of the healthcare programmes, crowded environmental settings and population movement due to the war. Outbreaks are reported of gastrointestinal diseases, including suspicion of cholera and polio. Other respiratory virus outbreaks are expected to occur, like measles, COVID-19, influenza. Most of these diseases are preventable, however the vaccine programme in Ukraine is facing vaccine shortages in autumn 2022 and 2023.

The main groups of patients required continued medical care through medical evacuation, those suffering from chronic diseases illness, such as cancer and the victims of the war, with different types of war trauma, including burns, which require reconstructive surgery, rehabilitation and long term specialised care. Also, most of the patients evacuated to the

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<sup>143</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

<sup>144</sup> 2020/0322 (COD), not yet published in the Official Journal.

Member States / EEA countries suffered from an infection which they had acquired during hospitalisation in Ukraine, with antimicrobial resistant agents.

In accordance with Articles 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the WHO is the eligible legal entity to implement this action. The WHO 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, and therefore, the WHO 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 policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a), (b), (c) and (j), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objective of the action is to reinforce the prevention, preparedness and response capacities for all threats (chemical, biological and radio-nuclear threat) in Ukraine and neighbouring countries / countries participating in the EU4Health Programme through the coordination with other existing EU Mechanisms as for instance the Union Civil Protection Mechanism (UCPM) and in collaboration with the WHO. The main priorities are to:

- a) support the national and cross-border prevention, preparedness and response capacities, including crisis coordination and inter-sectorial collaboration;
- b) strengthen health information management by reinforcing surveillance and early warning and response system for possible CBRN events;
- c) develop an efficient emergency care system, including the hospital and emergency medical team capacities for response to mass events;
- d) reinforce prevention, detection and control of prevalent infectious diseases, ensuring continuation of essential programmes for health promotion, prevention and healthcare for priority causes of illness and death.

Planned activities include to:

- a) reinforce surveillance and preparedness and response to CBRN events, including laboratory preparedness capacities;
- b) establish an alert system for detection and response to large scale CBRN events, increasing the Western Ukraine facilities and EU bordering countries capacities and reinforce the Medical hubs operations, established in Poland, Romania and Slovakia, including the patients information data management, infection prevention and control

(IPC) procedures;

- c) provide support to emergency health operations, including emergency operation coordination at first line hospitals, develop hospital preparedness, create procedures for mass medical evacuation and response for CBRN events;
- d) develop emergency medical care human resources capacities, by assessing the current needs, create a training for first assessment and specialised care, including management of trauma patients, decontamination of patients exposed to chemical and radio-nuclear events and healthcare acquired infection, infection prevention and control (IPC) procedures;
- e) support planning, recovery and restoring the public health and health security capacities, including a robust alert and information system, by improving health system governance and resilience to cope with the current health crisis;
- f) foster international cooperation and provide a platform for strengthening global health, specifically between the WHO and the Union in the World Health Summit 2023<sup>145</sup>.

#### **EXPECTED RESULTS AND IMPACT**

- a) Prevention, preparedness and response plans for mass events, trauma and possible CBRN incidents;
- b) Reinforcement of the surveillance and an early warning and response system for mass events for CBRN threats;
- c) Strengthened emergency health operations of first line hospitals and emergency medical teams;
- d) Improved health professionals capacities to address trauma, chemical, radio-nuclear events and healthcare acquired infections.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
CP-CA-23-04	Q2-Q3/2023	EUR 4 300 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>146</sup>	WHO

<sup>145</sup> The World Health Summit will organise specific sessions on crisis preparedness. Due to the global impact of the Russian war of aggression against Ukraine the World Health Summit is the best platform to steer these discussions.

<sup>146</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.



## **CR-CA-23-42 Cancer inequalities registry: biennial reports and index by the OECD**

### **Policy context**

As one of the 10 flagship initiatives of Europe's Beating Cancer Plan, the Commission is setting up a Cancer Inequalities Registry as a systematic surveillance and reporting mechanism to track the cancer situation in the Union. Building on (mainly) existing data and indicators collected for instance through the augmented European Cancer Information System, and the European Statistical System (Eurostat), the Cancer Inequalities Registry is expected to make comparable up-to-date quantitative cancer indicators available in a systematic and easily accessible way to the general public and policy-makers.

This action will follow up on the first evidence made available through the Registry and its 2023 Country Profiles and those for 2024. It will provide similar publications in 2025 and 2026, allowing policy makers and researchers to track progress over time. It will, furthermore, investigate the possibility to increase the comparability of data and more clearly track progress in crucial areas, e.g. by constructing an index that can measure the progress of cancer related inequalities in the Union. This index will give more visibility to areas that need improvement and ultimately support policy makers to design more effective cancer inequalities measures.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the the Organisation for Economic Co-operation and Development (OECD) is the eligible legal entity to implement this action. The OECD has a crucial leadership, a 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, 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 implementation of Europe's Beating Cancer Plan flagship initiative to establish a Cancer Inequalities Registry to reduce cancer inequalities across the Union, and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (j), of Regulation (EU) 2021/522.

### **OBJECTIVES, SCOPE AND ACTIVITIES**

The aim of this action is to make available quantitative data and contextual qualitative analysis of the cancer situation in the Member States in an easily accessible and digestible form. The cancer situation and trends in the Union and the Member States will be monitored, including at sub-national level and for specific socioeconomic groups, to identify areas of potential action and to guide investment decisions at EU and national level. These activities will provide systematic and comparable information and analysis on the cancer situation in Member States and at EU level, including on inequalities between and within Member States to inform EU investment decisions in cancer control.

In regularly published analytical reports the available quantitative data will be contextualised and complemented by qualitative information in relation to EU and national cancer control policies identifying trends, gaps and inequalities, with a view to informing and steering future investment decisions at EU and national level. In particular, the action will include the following activities:

- a) development of a quantitative measurement framework combining and weighing relevant indicators;
- b) publication of Cancer Country Profiles for all 27 Member States, Iceland and Norway;
- c) publication of an Overarching Report on Cancer Inequalities in Europe.

#### **EXPECTED RESULTS AND IMPACT**

The establishment of a Cancer Inequalities Registry to map key cancer data is expected to result in the identification of inequalities between Member States and regions. A consolidated view of the inequality landscape across the Union will assist in targeting investments and interventions at EU, national and regional level to address trends, disparities and inequalities between Member States and regions. The expected impact will be a reduction in measurable disparities in cancer prevention and care across the Union.

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
CR-CA-23-42	Q2/2023	EUR 2 500 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>147</sup>	OECD

<sup>147</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

## **HS-CA-23-45-01 State of Health in the EU – 5<sup>th</sup> cycle: ‘Health at a Glance 2024: Europe’, Country Health Profiles 2025 and Synthesis Report 2025**

### **POLICY CONTEXT**

The State of Health in the EU is a two-year recurring project launched in 2016 by the Commission in collaboration with the OECD and the European Observatory on Health Systems and Policies, which is a WHO-hosted partnership. The project responds to the necessity of the Member States and the Commission to improve the knowledge base in the area of health, health systems and health policies in the Union.

With the advent of the COVID-19 pandemic, the pre-existing need to regularly develop and make use of high-quality data and analysis for health policymaking has become even more acute. In addition, comparable and robust data can help countries to better understand how to improve the effectiveness, accessibility and resilience of their national health systems. In this context, the deliverables from the State of Health in the EU cycle provide a useful compass to identify health challenges and health system weaknesses and strengths.

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

Following four successful cycles of the State of Health in the EU, the fifth cycle will keep striving to offer more impactful knowledge-brokering products to the Member States.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the WHO - European Observatory on Health System and Policies is the eligible legal entity to implement this action. The WHO 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, the WHO - European Observatory on Health System and Policies is the sole entity with the required expertise and capacity to implement the action in collaboration with the OECD.

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

### **OBJECTIVES, SCOPE AND ACTIVITIES**

Based on the revamped design of the fourth project iteration (2022-2023) included in the EU4Health 2021 work programme (HS-g-14.2.1.1 “State of Health in the EU (4th cycle): ‘Health at a Glance: Europe 2022’, Country Health Profiles 2023 and strengthened Voluntary Exchanges”), the 2024-2025 project cycle will continue producing a wide array of health systems knowledge-brokering products. On top of the Health at a Glance: Europe and Country Health Profiles, the project will also produce a Synthesis Report accompanying the Country Health Profiles, and will undertake the translation of the Country Health Profiles in their respective official language(s) and carry out dissemination activities.

The main activities and deliverables that are to be carried out are the following:

- a) Health at a Glance 2024: Europe – a new edition with new thematic chapters and updated sections of health indicators.
- b) Country Health Profiles 2025 - a new edition of 29 profiles (Member States plus Norway and Iceland).
- c) State of Health in the EU - Synthesis Report 2025. This new deliverable will substitute the “Companion Report” – a staff working document that Commission services developed in parallel with the Country Health Profiles in previous project cycles.
- d) Infographics for each of the three products above.
- e) Update and further development of the web-based data visualisation tools developed as part of the previous (2022-2023) project cycle.

#### **EXPECTED RESULTS AND IMPACT**

In the short term, the State of Health in the EU cycle will support Member States by strengthening the analytical base on the performance of their health systems and contribute to evidence-based policy making. It will deliver country-specific data in a comparative, analytical perspective, and will provide national authorities with a library of high-quality resources and support for the development of more effective health system investments, policies and reforms.

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

#### **INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Call topic/sub-topic</b>	<b>Estimated call publication</b>	<b>Budget</b>
HS-CA-23-45-01	Q3/2023	EUR 1 750 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Type of applicants targeted</b>
Indirect management	SANTE/HaDEA <sup>148</sup>	WHO

<sup>148</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

## **HS- CA-23-45-02 State of Health in the EU – 5th cycle: ‘Health at a Glance 2024: Europe’, Country Health Profiles 2025 and Synthesis Report 2025**

### **POLICY CONTEXT**

The State of Health in the EU is a two-year recurring project launched in 2016 by the Commission in collaboration with the OECD and the European Observatory on Health Systems and Policies which is a WHO hosted partnership. The project responds to the necessity of the Member States and the Commission to improve the knowledge base in the area of health, health systems and health policies in the Union.

With the advent of the COVID-19 pandemic, the pre-existing need to regularly develop and make use of high-quality data and analysis for health policymaking has become even more acute. In addition, comparable and robust data can help countries to better understand how to improve the effectiveness, accessibility and resilience of their national health systems. In this context, the deliverables from the State of Health in the EU cycle provide a useful compass to identify health challenges and health system weaknesses and strengths.

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

Following four successful cycles of the State of Health in the EU, the fifth cycle will keep striving to offer more impactful knowledge-brokering products to Member States.

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 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, the OECD is the sole entity with the required expertise and capacity to implement the action in collaboration with the WHO-European Observatory on Health Systems and Policies.

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

### **OBJECTIVES, SCOPE AND ACTIVITIES**

Based on the revamped design of the fourth project iteration (2022-2023), included in the EU4Health 2021 Work programme (HS-g-14.2.1.2 State of Health in the EU (4th cycle): ‘Health at a Glance: Europe 2022’, Country Health Profiles 2023 and strengthened Voluntary Exchanges), the 2024-2025 project cycle will continue producing a wide array of health systems knowledge-brokering products. On top of the Health at a Glance: Europe and Country Health Profiles, the project will also produce a Synthesis Report accompanying the

Country Health Profiles, and will undertake the translation of the Country Health Profiles in their respective official language(s) and carry out dissemination activities.

The main activities and deliverables that are to be carried out are the following:

- a) Health at a Glance 2024: Europe – a new edition with new thematic chapters and updated sections of health indicators.
- b) Country Health Profiles 2025 - a new edition of 29 profiles (Member States plus Norway and Iceland).
- c) State of Health in the EU - Synthesis Report 2025. This new deliverable will substitute the “Companion Report” – a staff working document that Commission services developed in parallel with the Country Health Profiles in previous project cycles.
- d) Infographics for each of the three products above.
- e) Update and further development of the web-based data visualisation tools developed as part of the previous (2022-2023) project cycle.

### EXPECTED RESULTS AND IMPACT

In the short term, the State of Health in the EU cycle will support Member States by strengthening the analytical base on the performance of their health systems and contribute to evidence-based policy making. It will deliver country-specific data in a comparative, analytical perspective, and will provide national authorities with a library of high-quality resources and support for the development of more effective health system investments, policies and reforms.

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

### INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
HS-CA-23-45-02	Q3 /2023	EUR 1 750 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>149</sup>	OECD

<sup>149</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

## **HS-CA-23-57 Improving the availability, accessibility and affordability of medicinal products**

### **POLICY CONTEXT**

The Pharmaceutical Strategy for Europe mentions that the Commission will support mutual learning among Member States to reach the objective of improving access to affordable medicines in the Union. Prices and pricing decisions influence access to cost-effective and affordable medicines.

Member States have sometimes missing capacity on pricing and reimbursement in particular when they have to produce methodologies for objective and verifiable criteria on the cost-effectiveness of medicines and their affordability. The OECD has undertaken several projects on this matter and will further explore avenues to address the challenges of access to medicines and not only in Europe.

Therefore, the OECD can support the Commission and Member States to meet the objective of the Pharmaceutical Strategy for Europe and on how to improve the availability, accessibility and affordability of medicinal products.

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 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.

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

### **OBJECTIVES, SCOPE AND ACTIVITIES**

The objective of this action is to implement the strategic cooperation in relation to pharmaceuticals, and making use of the OECD expertise in the implementation of the EU affordability initiative as described in the Pharmaceutical Strategy for Europe.

The OECD will perform the following activities:

- a) analytical and evidence based working activities to support Member States on the pricing and reimbursement of medicinal products;
- b) active dialogue with the EU NCAPR on the mutual learning and policy making at national level;
- c) reinforcement of Member States' capacity building to meet the Pharmaceutical strategy's objective of improving patients access to affordable medicines.

## EXPECTED RESULTS AND IMPACT

The results of the activities will be:

- a) production of the OECD reports, working papers and guidance documents on pharmaceuticals;
- b) organising workshops, seminars and capacity building activities to be channelled into the work of Member States on pricing and reimbursement;
- c) knowledge transfer and expertise to the Member States and the Commission.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
HS-CA-23-57	Q3/2023	EUR 600 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>150</sup>	OECD

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<sup>150</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.



## **HS- CA-23-52 Council of Europe - European Directorate for the Quality of Medicines & HealthCare (EDQM) - Support for Pharmaceuticals**

### **POLICY CONTEXT**

Directives 2001/83/EC<sup>151</sup> and 2001/82/EC<sup>152</sup> aim to ensure the quality of medicines in the European Economic Area by, inter alia, the development and maintenance of the European Pharmacopoeia. The Union is a party to the Convention on the European Pharmacopoeia of the Council of Europe. The action aims at ensuring the harmonisation of quality standards vested in the Union pharmaceutical legislation, by facilitating the placing on the market of medicines in all the Member States, and the availability of medicines for the whole European population by contributing to the work on the European Pharmacopoeia.

The European Pharmacopoeia (Ph. Eur.) is a single reference work for the quality control of medicines. The official standards it contains provide a scientific basis for quality control during the entire life cycle of a product.

The Pharmacopoeia needs continuous maintenance and updates as the standards are legally binding as laid down in the Council of Europe Convention on the Elaboration of a European Pharmacopoeia, Union law and the national pharmaceutical legislation.

This action supports the obligation of ensuring a high level of human health in accordance with Article 168 (1) of the TFEU and the policy priority of the European Health Union.

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

### **OBJECTIVES, SCOPE AND ACTIVITIES**

The activities of this action will focus on:

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<sup>151</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L311, 28.11.2001, p.67).

<sup>152</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L311, 28.11.2001, p.1).

- a) maintaining and coordinating the Biological Standardisation Programme (BSP);
- b) maintaining and coordinating the European Official Medicines Control Laboratories (OMCL) Network;
- c) maintaining and coordinating the EDQM terminology activities;
- d) supporting the ongoing work on the European Pharmacopoeia;
- e) providing expertise to the Commission on the placing on the market and the surveillance of medicinal products.

## EXPECTED RESULTS AND IMPACT

The results are the following:

- a) adequate and effective surveillance of the quality of marketed medicines in Europe;
- b) maintenance and further improvement of the harmonised identification of medicinal products in the Union and globally;
- c) development and harmonisation of quality standards in line with the Union pharmaceutical legislation;
- d) coordination of the network of national official medicines control laboratories (OMCLs) that verify the quality of medicinal products, as required by the Union legislation, e.g. Batch Release and Market Surveillance;
- e) harmonised quality standards and reference materials for biologicals in line with the EU efforts for the protection of animals.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
HS-CA-23-52	Q3/2023	EUR 4 600 000
<b>Procedure type</b> Indirect management	<b>Implemented by</b> SANTE/HaDEA <sup>153</sup>	<b>Entity</b> Council of Europe - European Directorate for the Quality of Medicines & HealthCare

<sup>153</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

## **HS-CA-23-70-01 Improving access to healthcare for refugees<sup>154</sup> and people displaced from Ukraine benefitting of temporary protection in Member States.**

### **POLICY CONTEXT**

Directive 2001/55/EC<sup>155</sup> and the Council Implementing Decision (EU) 2022/382<sup>156</sup> offered benefits to persons enjoying temporary protection. One of the rights is access to medical care. Access to healthcare is also one of the principles of the European Pillar of Social Rights and the Action Plan<sup>157</sup> adopted to boost the implementation of the Pillar stressed that efforts to improve access to healthcare should focus in particular on the needs of vulnerable populations.

However, effective access to services depends on a different number of factors, being the knowledge of the rights, knowledge of the language, having a relation with the community where the healthcare service is operating, stability in the residence, sense of permanence, etc.

At the same time, an extraordinary number of displaced persons can place undue stress on the health system of a Member State that could be focused just on some regions or equally distributed in the whole country. This burden on the health systems could also be concentrated just in a small number of countries, or that could be the initial situation and then the distribution among the Member States could be spread out with the time.

The current displaced population from Ukraine is massive and mainly composed of women, children, elderly and sick people, of vulnerable persons, different to other migratory trends, which were mainly driven by economic migration or displacement of population of smaller size. That also means that there could be an increased number of chronic conditions and persons in treatment, and a number of children whose the vaccination coverage needs to be established and put up with the one of the country of arrival. Furthermore, people fleeing Ukraine have specific health needs: they are traumatised, they may have experienced violence, and their health may also have deteriorated because their basic needs, not related to clinical care, are not met.

This displaced population, in principle, is expected to return home as soon as the situation in their country is stable. This means that health systems need support to ensure access to services for the additional inflow of patients and for patients who may have specific needs for a transitional period. Finally, due to a variety of reasons, refugees and displaced people may deter or delay looking for healthcare and this could lead to non-diagnosed pathologies,

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<sup>154</sup> The term refugees is used in a more international context, with the definition of IOM/UNHCR “displaced person who has crossed national borders and who cannot or is unwilling to return home due to well-founded fear of persecution”.

<sup>155</sup> 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 (OJ, 7.8.2001, L 212 p. 12).

<sup>156</sup> Council Implementing Decision (EU) 2022/382 of 4 March 2022 establishing the existence of a mass influx of displaced persons from Ukraine within the meaning of Article 5 of Directive 2001/55/EC, and having the effect of introducing temporary protection (OJ, L71, 4.3.2022 p.1).

<sup>157</sup> [The European Pillar of Social Rights Action Plan | European Commission \(europa.eu\)](#).

increased use of emergency facilities, worse health, dissemination of infectious diseases non-treated and increased costs for health systems due to late diagnosis.

In accordance with Articles 7(1) and 13 (1) point (b) of Regulation (EU) 2021/522 the WHO is the eligible legal entity to implement this action. The WHO 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, and therefore, the WHO is the sole entity with the required expertise and capacity to implement the action.

Member States have expressed commitments in international fora to work on issues pertaining to refugee and migrant health, such as the WHO Regional Committee in September 2022 and the High-level Meeting on Health and Migration in March 2022.

This activity will need full coordination and complementarity with the International Organization for Migration (IOM) (action HS-CA-23-45-70-02).

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 policy priority to respond to health inequalities and to improve the access to healthcare and it implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3, point (d)) through the specific objectives defined in Article 4, points (g), (i) and (j), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

- a) working with authorities responsible for health to adjust the health coverage to meet the needs of refugees and displaced persons benefitting of temporary protection;
- b) analysis on how the health systems of the Member States have been affected due to increased numbers of refugees and the barriers and challenges of the refugees in accessing health services. This assessment should take into account the views of authorities responsible for health at national and subnational level, views of health professional organisations and of relevant NGOs and beneficiaries;
- c) providing health mediators to ensure smooth access to healthcare for refugees, that don't know the system of the receiving countries;
- d) establishment of networks of health professionals working with refugees to facilitating the access and encouraging the use of the regular health services of the Member States by the displaced persons and supporting those professionals including via continuous education;
- e) developing pilots to integrate health professionals who are refugees in the health systems of the Member States;
- f) increasing the vaccination coverage of children and adults;
- g) establishment of health promotion programmes adapted to the reality of the displaced persons.

## EXPECTED RESULTS AND IMPACT

- a) increase capacities of health systems to cope with a displaced population;
- b) contribute to fight health inequalities in the Union, increasing the care for vulnerable populations;
- c) contribute to the health security in the Union guaranteeing that everybody has access to the necessary healthcare and prevention and treatment of diseases, including infectious diseases.

## INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
HS-CA-23-70-01	Q4/2023	EUR 2 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>158</sup>	WHO

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<sup>158</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.

## **HS-CA-23-70-02 Improving access to healthcare for refugees<sup>159</sup> and people displaced from Ukraine benefitting of temporary protection in Member States.**

### **POLICY CONTEXT**

Directive 2001/55/EC<sup>160</sup> and the Council Implementing Decision (EU) 2022/382<sup>161</sup> offered benefits to persons enjoying temporary protection. One of the rights is access to medical care. Access to healthcare is also one of the principles of the European Pillar of Social Rights and the Action Plan<sup>162</sup> adopted to boost the implementation of the Pillar. In the Action Plan, it is stressed that efforts to improve access to healthcare should focus in particular on the needs of vulnerable populations.

However, effective access to services depends on a different number of factors, such as the knowledge of one's rights, knowledge of the language, having a relation with the community where the healthcare service is operating, stability in the residence, sense of permanence, etc.

At the same time, an extraordinary number of displaced persons can place undue stress on the health system of a Member State that could be focused just on some regions or equally distributed in the whole country. This burden on the health systems could also be concentrated just to a small number of countries, or that could be the initial situation and then the distribution among the Member States could be spread out with the time.

The current displaced population from Ukraine is massive and mainly composed of women, children, elderly and sick people, of vulnerable persons, and is different from populations of earlier migratory trends, which were mainly driven by economic migration or displacement of populations of smaller size. That also means that there could be an increased number of chronic conditions and persons under treatment, and a number of children where the vaccination coverage needs to be established and put up with the one of the country of arrival. Furthermore, people fleeing Ukraine have specific health needs than the general population: they are traumatised, they may have experienced violence, and their health may also have deteriorated because their basic needs, not related to clinical care, are not met.

This displaced population, in principle, is expected to return home as soon as the situation in their country is stable. This means that health systems need support to ensure access to services for the additional inflow of patients and for patients who may have specific needs for a transitional period. Finally, due to a variety of reasons, refugees and displaced people may deter or delay seeking healthcare and this could lead to non-diagnosed pathologies, increased

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<sup>159</sup> The term refugees is used in a more international context, with the definition of IOM/UNHCR “displaced person who has crossed national borders and who cannot or is unwilling to return home due to well-founded fear of persecution”.

<sup>160</sup> 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 (OJ, 7.8.2001, L 212 p. 12).

<sup>161</sup> Council Implementing Decision (EU) 2022/382 of 4 March 2022 establishing the existence of a mass influx of displaced persons from Ukraine within the meaning of Article 5 of Directive 2001/55/EC, and having the effect of introducing temporary protection (OJ, L71, 4.3.2022 p.1).

<sup>162</sup> [The European Pillar of Social Rights Action Plan | European Commission \(europa.eu\)](#).

use of emergency facilities, worsened health, dissemination of non-treated infectious diseases and increased costs for health systems due to late diagnosis.

In accordance with Article 7(1) and Article 13 (1), point (b), of Regulation (EU) 2021/522 the IOM is the eligible legal entity to implement this action. The IOM has a crucial leadership, and a convening and coordination role in migrant health, and in strengthening multilateral cooperation and therefore, the IOM is the sole entity with the required expertise and capacity to implement the action.

Member States have expressed commitments in international fora to work on issues pertaining to refugee and migrant health, such as the WHO Regional Committee in September 2022 and the High-level Meeting on Health and Migration in March 2022.

This activity will need full coordination and complementarity with the WHO (action HS-CA-23-45-70-01).

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 policy priority to respond to health inequalities and to improve the access to healthcare and it implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3, point (d)) through the specific objectives defined in Article 4, points (g), (i) and (j), of Regulation (EU) 2021/522.

#### **OBJECTIVES, SCOPE AND ACTIVITIES**

- a) working with authorities responsible for health to adjust the health coverage to meet the needs of refugees;
- b) providing health mediators to ensure smooth access to healthcare for refugees, that are not familiar with the system of the receiving countries;
- c) coordination of integrated services to maintain and improve the health status of displaced persons (such as co-operation of the health systems with NGOs and social workers, other governmental authorities, deployment of health teams to reach the refugee population, expanding assignment of health professionals to assess health needs of refugees and navigate them in the health systems);
- d) establishment of networks of health professionals working with refugees to facilitating the access and encouraging the use of the regular health services of the Member States by the displaced persons and supporting those professionals including via continuous education;
- e) establishment of health promotion programmes adapted to the reality of the displaced persons.

#### **EXPECTED RESULTS AND IMPACT**

- a) increased capacities of health systems to cope with a displaced population;
- b) contribution to the fight against health inequalities in the Union, increasing the care for vulnerable populations;

- c) contribution to the health security in the Union guaranteeing that everybody has access to the necessary healthcare and prevention and treatment of diseases, including infectious diseases.

**INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE**

<b>Topic/sub-topic</b>	<b>Estimated launch date</b>	<b>Budget</b>
HS-CA-23-70-02	Q4/2023	EUR 2 000 000
<b>Procedure type</b>	<b>Implemented by</b>	<b>Entity</b>
Indirect management	SANTE/HaDEA <sup>163</sup>	IOM

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<sup>163</sup> For actions implemented under indirect management, the delegation of these actions to HaDEA is subject to the adoption of the new Internal Rules authorising the signature of contribution agreements by executive agencies.