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ANNEX

ANNEX

to the

Commission Implementing Decision

on the financing of the programme for the Union´s action in the field of health ('EU4Health programme') and the adoption of the work programme for 2025

EU4Health work programme for 2025

Contents

INTRODUCTION

On 24 March 2021, Regulation (EU) 2021/522 of the European Parliament and of the Council[1] was adopted as part of the Multiannual Financial Framework for the 2021-2027 period. That Regulation established a programme for the Union's action in the field of health ('the EU4Health Programme').

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

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

The EU4Health Programme, as main financial instrument to fund the Union health initiatives, is implemented through annual work programmes. On 24 June 2021 the Commission adopted the 2021 work programme, on 14 January 2022 the Commission adopted the 2022 work programme, on 21 November 2022 the Commission adopted the 2023 work programme and on 5 December 2023 the Commission adopted the 2024 work programme. Four amendments have been adopted on 12 April 2022[2], on 25 July 2022[3], on 25 July 2023[4] and on 15 November 2024[5].

The EU4Health Programme supports the implementation of Union priorities such as the fight against the COVID-19 pandemic, the activities of the Commission's Health Emergency Preparedness and Response Authority ('HERA'), the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe[6], the EU Global Health Strategy, and the implementation of Union health legislation. The EU4Health Programme supports the extended mandates of the European Medicines Agency ('EMA')[7] and the European Centre for Disease Prevention and

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1 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).
2 C(2022) 2470 final.
3 C(2022) 5436 final.
4 C(2023) 5052 final.
5 C(2024) 7871 final.
6 Including the "Strategic Approach on Pharmaceuticals for the Environment" (COM(2019) 128)
7 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).

Control ('ECDC')[8] and, will support the further implementation of the Health Union Package, in subsequent work programmes. The Programme should also contribute to the objectives set out in the Commission communication 'The European Green Deal'[9], e.g. including its zero pollution objectives[10].

On 7 February 2024, the European Parliament and the Council reached an agreement on the revision of the Multiannual Financial Framework (MFF) for 2021-2027[11]. This revision was necessary to provide additional substantial support for Ukraine and to equip the MFF with the means to ensure that the Union can meet its legal obligations and address the most urgent priorities. The MFF revision involves redeployments within the Union budget to reduce its impact on national budgets, given ongoing fiscal consolidation efforts, including a redeployment of EUR 1 billion from the EU4Health Programme. Therefore, the prioritisation and careful allocation of the adjusted budget became even more critical, ensuring that every euro is directed towards maximising impact and supporting the European Health Union's strategic objectives.

The EU4Health work programme for 2025 consists of four overarching 'strands': (1) crisis preparedness; (2) health promotion and disease prevention; (3) health systems and healthcare workforce; and (4) digital. The (5) "flagship" strand includes cancer, and the new priorities 2025-2029 on cardiovascular and other non-communicable diseases.

In particular, the 2025 EU4Health work programme is addressing some of the new initiatives included in the mission letters from Commission President von der Leyen to the Commissioner for Health and Animal Welfare[12] and to the Commissioner of Equality, Preparedness and Crisis Management[13] and continue to support the implementation of the Europe's Beating Cancer Plan. It will also reinforce the implementation of the existing health legislation, notably on serious cross-border threats to health, health technology assessment, medical devices, substances of human origin, and pharmaceuticals. In the digital strand focus is on supporting the implementation of the European Health Data Space Regulation[14].

To optimise the added value and impact from investments funded wholly or in part through the budget of the Union, the Member States will implement the EU4Health Programme in overall consistency, synergy, and complementarity with other Union programmes[15], policies,

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

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

10 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil', COM/2021/400 final.

11 https://ec.europa.eu/commission/presscorner/detail/en/ip_24_681.

12 https://commission.europa.eu/about/organisation/college-commissioners/oliver-varhelyi_en.

13 https://commission.europa.eu/about/organisation/college-commissioners/hadja-lahbib_en.

14 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

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

instruments and actions, such as Horizon Europe. Through its EU Mission on Cancer[16], Horizon Europe will contribute to the implementation of some of the Europe's Beating Cancer Plan flagship initiatives and actions. The EU4Health work programme is aligned with the Strategic Technologies for Europe Platform ('STEP') to support investments in companies that contribute to preserving a European edge on critical biotechnologies. Reaping the full benefits of biotechnology can help the Union economy grow in respect of priorities such as sustainable development, public health, and environmental protection. In March 2024, the STEP Regulation entered into force to boost investments in critical technologies in Europe: clean and resource efficient technologies, digital and deep innovation technologies, and biotechnologies. STEP aims at mobilising funding from existing Union programmes to support the development and manufacturing of these critical technologies, while safeguarding and strengthening the respective value chains, as well as associated services and skills critical for and specific to the development and manufacturing of the final products. This work programme identifies the actions and indicative budgets in support of STEP objectives in the area of biotechnologies. Proposals meeting the minimum requirements indicated in the conditions of the STEP-relevant call for proposals will receive a STEP Seal[17].

This work programme sets out objectives and actions, including the resource allocation, for the implementation of the EU4Health Programme in 2025. In pursuing those actions, Member States will consider 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[18], for the purposes of achieving inclusive growth and a gender sensitive approach, where relevant.

On 11 February 2025, the European Parliament and the Council adopted Regulation (EU) 2025/327 on the European Health Data Space ('EHDS'). This Regulation aims at providing individuals faster and easier access to and control over their personal electronic health data (primary use). It will also allow certain health data to be reused for research and innovation purposes (secondary use). Both aspects are crucial for the development of innovative and personalised medicines. This work programme supports the rollout of MyHealth@EU (the cross-border infrastructure for the exchange of health data), the setting up of health data access bodies and the development of HealthData@EU (the cross-border infrastructure for supporting multi-country access requests), capacity building in primary and secondary uses of health data, development of the European Electronic Health Record exchange Format ('EEHRxF').

In accordance with Article 13 of Regulation (EU) 2021/522, the Commission intends to provide funding to eligible legal entities from Member States, third countries associated to it, or listed in the annual work programme, entities created under Union law or to international organisations such as health organisations, non-governmental organisations ('NGOs'), the private sector and other eligible legal entities. Unless otherwise stated, in this work programme 'Member States' authorities' means 'competent authorities responsible for health in the Member States or in third countries associated to the EU4Health Programme'.

With regard to third countries associated to the EU4Health Programme[19], their participation in actions under this work programme will be subject to compliance of their respective national

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16 European Mission – Cancer – Implementation Plan.

17 The STEP Seal is the Sovereignty Seal defined in Regulation (EU) 2024/795: Strategic Technologies for Europe Platform - European Union (STEP).

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

19 EU4Health programme 2021-2027 – a vision for a healthier European Union - European Commission.

systems with the Union legislation relevant to the specific action (such as Regulation (EU) 2016/679 of the European Parliament and of the Council (the 'General Data Protection Regulation')[20] when treatment of personal data is involved).

The participation of legal entities from third countries non-associated to the EU4Health Programme is possible where those third countries are listed in the annual work programme in accordance with Article 13(1)(a)(iii) of Regulation (EU) 2021/522.

LEGAL BASIS

Regulation (EU, Euratom) 2024/2509[21] of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1046/2018, (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, [22] and in particular Article 110(1) 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 2025

Based on the objectives defined in Regulation (EU) 2021/522, this work programme contains the actions to be financed and their total budget (Table 1). The budget breakdown for 2025 is indicated in Table 2.

TABLE 1: BUDGET LINES

BUDGET LINES	2025 (in EUR)
06 06 01	555 939 966
TOTAL	555 939 966[23]

The actions included in the annual work programmes can be implemented in direct management (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) 2024/2509.

Grants[24] are financial contributions by way of donation by the Commission to finance e.g. an action intended to help achieve a Union policy objective (action grants).

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

21 http://data.europa.eu/eli/reg/2024/2509/oj.

22 OJ L 193, 30.7.2018, p. 1.

23 Excluding contributions from associated EEA EFTA countries to the EU4Health Programme with an amount of EUR 15 288 349 for 2025, which represents 2.75% of the EU4Health budget, as well as contributions of EUR 119 000 from Candidate countries and Western Balkan potential candidates.

24 Articles 2(35) and 183(2) of Regulation (EU, Euratom) 2024/2509.

Procurement[25] means the acquisition by means of a contract of works, supplies or services and the acquisition or rental of land, buildings or other immovable property, by one or more contracting authorities from economic operators chosen by those contracting authorities.

TABLE 2: OVERVIEW OF FUNDING BY PROCEDURE

FUNDING	**2025 Budget** (in EUR)
Direct management	**479 897 315**
of which grants	195 464 733
of which procurement	281 702 582
of which for other expenditure	2 730 000
Indirect management (contribution agreements)	**91 450 000**
TOTAL	**571 347 315**

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

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

[25] Article 2(54) of Regulation (EU, Euratom) 2024/2509.

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

TABLE 3: BUDGET BY ACTION AREAS

STRANDS AND AREAS OF ACTION	**2025 budget** (in EUR)
1. CRISIS PREPAREDNESS (CP)	**380 995 165**
HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA)	357 645 165
ONE HEALTH SURVEILLANCE	15 000 000
IMPLEMENTATION OF THE REGULATION ON SERIOUS CROSS BORDER THREATS TO HEALTH	6 500 000
BIOLOGICAL AND CHEMICAL HAZARDS	1 000 000
MOSQUITO VECTOR MONITORING	600 000
STUDY ON THE IMPLEMENTATION OF THE EU ONE HEALTH ACTION PLAN AGAINST AMR	250 000
2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)	**7 605 000**
TOBACCO CONTROL POLICY	1 660 000
EUROPEAN REFERENCE NETWORKS AND ORPHANET	3 980 000
HEALTH POLICY PLATFORM AND SCIENTIFIC COMMITTEES	1 265 000
EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES PARTNERSHIP	700 000
3. CANCER, CARDIOVASCULAR AND OTHER NON-COMMUNICABLE DISEASES (CR/CV&NCDS)	**60 580 000**
CANCER SCREENING PROGRAMMES (GASTRIC, LUNG AND PROSTATE)	17 880 000
EUROPE'S BEATING CANCER PLAN ANNUAL EVENT AND ADMINISTRATIVE SUPPORT TO THE PLAN'S GOVERNANCE	200 000
SUPPORTING IMPLEMENTATION OF THE STRATEGIC AGENDA FOR MEDICAL IONISING RADIATION APPLICATIONS (SAMIRA)	11 500 000
A EUROPEAN FLAGSHIP INITIATIVE LEVERAGING AI AND HEALTH DATA FOR CARDIOVASCULAR HEALTH AND RELATED NON-COMMUNICABLE DISEASES: ADVANCING RISK PREDICTION, PREVENTION, TREATMENTS, PERSONALISED CARE AND REHABILITATION	20 000 000
HEALTHY LONGEVITY AND LIFELONG PREVENTION: CARDIOVASCULAR DISEASES	11 000 000

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)	**71 415 000**
STATE OF HEALTH IN THE EU	4 150 000
IMPLEMENTATION OF THE HEALTH TECHNOLOGY ASSESSMENT REGULATION	11 300 000
IMPLEMENTATION OF THE PHARMACEUTICAL LEGISLATION AND STRATEGY	16 800 000
IMPLEMENTATION OF THE CLINICAL TRIALS REGULATION	6 500 000
IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS	10 000 000
IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO MEDICAL DEVICES[26]	18 690 000
CROSS-BORDER HEALTHCARE	75 000
HEALTH UNION FELLOWSHIP PROGRAMME	1 400 000
EU GLOBAL HEALTH STRATEGY	2 500 000
5. DIGITAL (DI)	**39 686 810**
ENHANCING HEALTH DATA ACCESS BODIES	14 400 000
HEALTH DATA FOR BIOTECH INNOVATION: LEVERAGING THE EUROPEAN HEALTH DATA SPACE	14 386 810
ADMINISTRATIVE AND LOGISTICAL SUPPORT TO THE EHDS AND DIGITAL ACTIONS	1 000 000
DEVELOPMENT, DEPLOYMENT AND OPERATIONS OF THE CENTRAL SERVICES OF THE INFRASTRUCTURE ON PRIMARY USES OF HEALTH DATA, MYHEALTH@EU	2 500 000
DEVELOPMENT, DEPLOYMENT AND OPERATIONS OF THE CENTRAL SERVICES OF THE INFRASTRUCTURE ON SECONDARY USES OF HEALTH DATA, HEALTHDATA@EU	1 000 000
ACTIONS FOR EU-LEVEL INFRASTRUCTURES AND SERVICES IN THE EHDS	4 000 000
COMPLIANCE CHECKS FOR MYHEALTH@EU	2 400 000
6. OTHER ACTIONS	**11 065 340**
ORGANISATION OF CONFERENCES AND EVENTS	600 000
COMMUNICATION ACTIVITIES	4 838 340
IT RECURRENT ACTIVITIES	4 000 000
TRANSLATION SERVICES	210 000

[26] Including the Joint assessment of Notified Bodies.

European Health and Digital Executive Agency (HaDEA) expert evaluators and Monitors	772 000
Enlargement conformity Study	425 000
International medical Device Regulatory forum	200 000
Reimbursement of experts participating in Commission controls and audits in the pharmaceutical field	20 000

ELIGIBILITY, SELECTION AND AWARD CRITERIA FOR ACTION GRANTS

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

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

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

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

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

The verification of the financial capacity shall not apply to international organisations and public bodies[27].

The Commission will assess proposals based on the following **award criteria**:

(a) relevance to the priorities of the call for proposals;

(b) quality of the proposed action;

(c) impact of the proposed action.

Grants shall involve co-financing[28]. 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[29]. In the case of direct grants awarded without a call for proposals to European Reference Networks ('ERNs') and to other transnational networks set out in accordance with Union law referred to in Article 13(6) of Regulation (EU) 2021/522, such grants may be up to 100 % of eligible costs[30].

The exceptional utility assessment and ranking of proposals shall be done by the contracting authority in accordance with the criteria described in the calls for proposals.

PROGRAMME PERFORMANCE MONITORING AND INDICATORS

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

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27 Article 201(5) and (6) of Regulation (EU, Euratom) 2024/2509.

28 Article 193(1) of Regulation (EU, Euratom) 2024/2509.

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

30 Article 8(4) of Regulation (EU) 2021/522.

A. GRANTS

1. CRISIS PREPAREDENESS (CP)

CP-g-25-01 Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA)

POLICY CONTEXT

HERA is responsible for improving preparedness and response to serious cross-border health threats through ensuring the availability and accessibility of relevant medical countermeasures. In the current geopolitical context, the use of chemical, biological or radio nuclear ('CBRN') agents poses a risk that authorities and healthcare providers need to prepare for. The threat landscape in the field of chemical and biological agents is evolving rapidly, facilitated by developments in biotechnology and artificial intelligence. While their probability is low, the impact of CBRN attacks can be high. One of the key pillars of preparedness, as for other health emergencies, are medical countermeasures.

With the synthesis of novel toxins and pathogens as a possibility, and many currently known chemical and biological threats, threat-agnostic and platform approaches are especially relevant. These can be leveraged for agents against which no or no specific medical countermeasures are available. While there are few new radio nuclear threats, the current range of medical countermeasures against them is overall very limited, meaning that a broader arsenal would help to better protect European residents.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures, to support innovation and access regarding such products and to ultimately enhance preparedness for future health emergencies with a focus on civilian capabilities. This action will complement the defence industry focused Counteract and Resilience projects financed under the European Defence Fund and thereby contribute to deeper civil-military cooperation and whole-of-society preparedness.

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

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(b).

OBJECTIVES, SCOPE AND ACTIVITIES

This action will focus on supporting advanced research on threat-agnostic medical countermeasures against CBRN agents and platform approaches to treat injuries from CBRN agents. These can include personal protective equipment, diagnostics, therapeutics, vaccines, as well as medical devices.

The objective is to improve the Union's readiness to respond to intentional health threats, including cross-border ones, by supporting the development of medical countermeasures to biological, chemical and radio-nuclear agents for which there currently are no or only limited treatment options.

The range of activities include an end-to-end approach to bridge the gap between advanced research, innovation, market access and deployment by supporting:

- Advanced research and development ('R&D') to support the development of medical countermeasures;
- Involving end users and security practitioners to bring the research products closer to market readiness; and
- Support research into market readiness or facilitate tech and entrepreneurial skills development.

This will be done in synergy with relevant Horizon Europe[31] and European Defence Fund[32] actions.

EXPECTED RESULTS AND IMPACT

This action is expected to increase the preparedness of the Union to respond to CBRN threats and improve the availability of medical countermeasures against these threats. It should advance one or more medical countermeasures against CBRN threats along the steps towards regulatory approval and market readiness. In particular:

- For countermeasures against biological threats, this includes vaccines, therapeutics (such as antivirals, small molecules, antimicrobials, monoclonals and polyclonals).
- For countermeasures against chemical agents, this includes antidotes, supportive treatments, and innovation in application devices or techniques.
- For countermeasures against radio-nuclear agents, treatments against acute radiation syndrome, against bone marrow suppression, and decorporation agents after exposure to radioactive substances.
- For Personal Protective Equipment ('PPE'), the focus is on reusable respiratory PPE and protection suits.
- For detection and diagnostics, a special focus is on tests that can rapidly detect individual or broad range of chemical and biological agents, including biotoxins.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for proposals – CP-g-25-01	Q3-Q4/2025	EUR 20 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grant)	HaDEA	Secondary or higher education establishments,

[31] Cluster 3: "Civil security for society", Destinations: "Better protect the EU and its citizens against Crime and Terrorism"; "Resilient Infrastructure"; "Disaster-Resilient Society for Europe" and "Strengthened Security Research and Innovation".

[32] European Strategic alliance for research, development and innovation on medical countermeasures against CBRN threats (RESILIENCE).

		research organisations, hospitals, expert networks including ERNs, security practitioners, end users, other private entities or public bodies and public authorities

CP-g-25-02 Direct grants to Member States' authorities for the scaling up of national systems for vector threat detection and control capacities (HERA)

POLICY CONTEXT

Climate change poses significant challenges to public health, notably through the alteration of environments that foster the spread of vector-borne diseases ('VBDs') along with increasing trade and migration. Rising temperatures, changing precipitation patterns, and increased humidity have created more hospitable conditions for the breeding and proliferation of invasive mosquito populations across Europe. These changes have facilitated the northward and upward migration of species such as *Aedes albopictus*, and *Aedes aegypti* and *Culex* species, known carriers of mosquito-borne viral diseases such as the re-emerging Dengue, Zika, Chikungunya, and West Nile viruses.

As these invasive species establish themselves more broadly within Union borders, the risk of outbreaks of these diseases increases, necessitating a robust and proactive response. The Union recognises the urgent need to strengthen Member States' capabilities to effectively monitor and control vector populations, assess their potential for transmitting non-endemic diseases in Europe, and evaluate the development of insecticide resistance.

Through this action, HERA seeks to fortify its collective epidemiological resilience, ensuring a coordinated and efficient response to the globalisation of emerging health threats by supporting the development and/or reinforcement of national systems for vector threat detection and control. This is in line with the Commission Communication introducing HERA[33] which announced work towards strengthening environmental monitoring.

It is expected that grantees will collaborate with the European centre for Disease Prevention and Control ('ECDC'), in order to ensure synergies and complementarities with action "CP-CA-25-87 prevention of the establishment of the dengue, chikungunya and Zika transmitting mosquitoes" and other on-going actions that partially include vector control (e.g. One Health Surveillance'; 'Improving and Strengthening national systems') and with relevant Horizon Europe actions on Climate Change and Health. This action will be implemented in close collaboration with the European Centre of Disease Control ('ECDC') the European Environmental Agency ('EEA'). Where possible, synergies should be also sought with the action supported under CP-g-25-08.

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 for threat detection including vector control measures.

[33] Communication COM(2021) 576 final: "Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union".

This action contributes to the horizontal policy priority aimed at fighting climate change.

This action implements the EU4Health Programme's general objectives of strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-border threats to health in the area of medical countermeasures and protecting people in the Union from serious cross-border threats to health (Article 3, point (b), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (b) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This joint action seeks to:

- scale up capacities by developing and/or enhancing national vector threat detection systems and improving vector control programmes;
- aligning with broader Union health and environmental goals to protect public health and address the risks posed by vector borne diseases and more generally the impacts of climate change;
- assess the effectiveness of these vectors in transmitting and spreading exotic diseases across Europe; and
- bolster laboratory capabilities for monitoring insecticide resistance in vectors.

The joint action will establish programmes to monitor vector abundance and distribution and assess infection rates across a range of species. Grantees are expected to develop and implement countermeasures for the control of disease-transmitting vectors, including physical, biological, and chemical methods, complemented by public outreach campaigns. The joint action should also focus in ensuring interdisciplinary collaborations among epidemiologists, entomologists, public health officials, veterinarians, and ecologists to drive international partnerships, optimise existing datasets, and deepen the understanding of global insect population dynamics.

EXPECTED RESULTS AND IMPACT

This action is expected to:

a) increase capacity to monitor, understand and control vector populations across Member States.
b) provide timely and accurate data on vector abundance and distribution.
c) control vector population to mitigate the spread of VBDs, reducing infection rates and improving public health outcomes.
d) contribute to resilient, sustainable programmes for managing VBDs.
e) mitigate the long-term health impacts of VBDs by maintaining robust surveillance and control measures.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grant to Member States – CP-g-25-02	Q3-Q4/2025	EUR 10 000 000

Procedure type	Implemented by	Type of applicants targeted
Direct grants to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

CP-g-25-03 Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)

POLICY CONTEXT

The emergence and re-emergence of vector-borne diseases ('VBDs') present a growing public health challenge within the Union. As vectors expand their geographical reach due in part to climate change and global travel, the Union faces increased threat from several VBDs, particularly mosquito-borne diseases such as Dengue, Zika, Chikungunya and West Nile fever. Furthermore, many VBDs are characterised not only by a lengthy incubation period but also by non-specific symptoms. Current diagnostic methods for these diseases often lack the necessary sensitivity and specificity, leading to significant rates of underdiagnosis and, consequently, delayed treatments and medical complications. This underdiagnosis not only affects the health outcomes of individuals but also impedes the effective epidemiological tracking and management of these diseases.

Developing cost-effective diagnostics for resource-limited settings is a priority for HERA, to facilitate timely diagnosis without central laboratory testing. There is therefore a critical need to develop new point of care diagnostic tests that are both more sensitive and more specific, cost-effective and capable of accurately detecting these diseases early in their onset. Additionally, the ability to rapidly diagnose VBDs is essential for initiating timely treatment and controlling outbreaks. Rapid diagnostic tests can significantly enhance response efforts by healthcare providers and public health officials, reducing the spread and impact of infections.

This call for proposals aims to support the development of innovative diagnostic technologies that address these needs. By fostering advancements in diagnostics, the Union seeks to improve health surveillance, enhance disease prevention, and ensure better health outcomes for its citizens, thereby strengthening the overall resilience of its health systems against VBDs.

This action contributes to the horizontal policy priority aimed at fighting climate change.

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

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(a).

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to:

- enhance disease detection, reduce misdiagnoses, and improve patient outcomes by broadening the diagnostic toolkit, with a focus on rapid tests.
- advance early detection of VBDs through the development of novel diagnostic tests that identify these diseases at an early stage, enabling timely treatment and control.
- increasing the accuracy and specificity of existing diagnostic assays to better identify VBD pathogens, thus minimising misdiagnoses.

The activities conducted under this action will focus on supporting late-stage development of medical devices, bringing them to (near-) market; improvement of existing products in terms of accessibility, affordability, or accuracy; or, in case of unmet needs, aid the creation of

innovative solutions. Supported actions will need to advance beyond the current R&I status and, where applicable, must also take into account ongoing Union projects, such as under Horizon Europe, guaranteeing complementary. This will expand diagnostic capabilities to address emerging and re-emerging pathogens in the Union, by providing advanced tools to monitor and respond to outbreaks.

Updating diagnostic technologies to improve accuracy, speed, and accessibility and the optimisation of diagnostic technologies such as molecular assays and serological tests, should be supported by evidence on novel antigens or genetic sequences, including clinical testing.

EXPECTED RESULTS AND IMPACT

This action is expected to:

a) improve diagnostic capabilities that will lead to earlier detection of VBDs, enabling prompt treatment initiation and reducing disease transmission.
b) develop new diagnostic tests to stimulate research and innovation in the field of VBDs.
c) support global health initiatives focused on attaining goals for international health security.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for proposals – CP-g-25-03	Q3-Q4/2025	EUR 10 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grant)	HaDEA	Secondary or higher education establishments, research organisations, hospitals and other healthcare institutions, NGOs, developers and other private entities or public bodies with an expertise in diagnosis development

CP-g-25-04/05 Direct grant(s) to Africa Centres for Disease Control and Prevention (Africa CDC) and the African Society for Laboratory Medicine (ASLM), and to Asia Pathogen Genomics Initiative (Asia PGI) to support wastewater surveillance for health threats' early detection (HERA)

POLICY CONTEXT

Wastewater surveillance has demonstrated to be a valuable source of important additional data that can support early detection of outbreaks, cost effective targeting of diagnostics, and also augment uptake of risk communications, among other uses. Such wastewater surveillance has also been successfully deployed for many years for polio and has been more recently trialled for other targets such as typhoid, cholera and antimicrobial resistance. Wastewater surveillance plays a significant role in the development and deployment of medical countermeasures by providing critical early warnings, monitoring trends in disease prevalence, and identifying emerging pathogens. The Commission Communication introducing HERA[34] already announced work towards strengthening environmental monitoring including wastewater-based surveillance.

Wastewater surveillance is essential to monitor and counteract outbreaks and pandemics, such as the COVID-19 pandemic and the Mpox outbreaks. In fact, during the Mpox 2022-2023 outbreak, wastewater surveillance successfully anticipated the emergence of clinical reporting of cases in several EU countries, as well as being proved to be a powerful tool to monitor e.g. travel hubs such as airports, identifying risk nodes and allowing prompt deployment of medical countermeasures. Additionally, as with SARS-CoV-2, wastewater surveillance was also successfully used in the Mpox outbreak to detect mutations and viral evolution, allowing for early detection of potential changes in transmission dynamics or disease severity.

Mpox remains a global concern. During 2024, Africa saw a step increase in cases and the emergence of a new Mpox subclade (Ib), which initially assessments estimated to be more transmissible, present higher virulence, and especially affected some vulnerable populations (i.e. children). Such concerns led WHO to declare this outbreak a "public health emergency of international concern" ('PHEIC') in August 2024, which was renewed in February 2025 and is ongoing. Sporadic cases of this new clade in European countries, co-circulating with remaining clades (Ia and II), along with newly unveiled data on the efficacy of existing medical countermeasures, support the need to continuously monitor this threat, not only in the EU but elsewhere in the world.

This case also supports the global nature of cross-border health threats and the need to increase cooperation beyond borders has been partially addressed with the launching of the global consortium for wastewater and environmental surveillance ('GLOWACON') and further shows that there is still a need to support and catalyse capacity building, alignment of testing methods and data sharing at regional level.

This action will support the establishment of a global early warning system for wastewater surveillance by supporting the advancement of wastewater surveillance in Africa and Asia, where capacity to detect emergent pathogens are still limited.

Therefore, this action aims to support:

a) the Africa Centres for Disease Control and Prevention ('Africa CDC'), which is the health agency of the African Union established to support public health initiatives and

[34] COM(2021) 576 final.

strengthen the capacity of public health institutions to detect, prevent, control and respond quickly and effectively to disease threats, and the African Society for Laboratory Medicine ('ASLM'), which is the first pan-African society for laboratory professionals, endorsed by the African Union. By leveraging the African continental mandate in leading wastewater surveillance activities of Africa CDC and the extensive expertise in international grant management and scientific excellence of ASLM, and also noting the collaboration already established between these entities for other Union-funded projects, both entities are the best suited to implement expected activities in Africa.

b) the Duke-NUS Medical School ('Duke-NUS'), which hosts and manages the Asia Pathogen Genomics Initiative ('Asia PGI'), bringing together a breadth of scientific and technical partners across 15 Asian countries to accelerate pathogen genomics as a critical tool to enhance outbreak preparedness and response capacity. In particular, Asia PGI seeks to advance wastewater surveillance in Asia as a critical early detection strategy for novel and endemic pathogens.

Since these three 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, and pursuant to Article 13(2) and (5) of Regulation (EU) 2021/522 they are considered eligible legal entities, being co-financed by international organisations. Their participation is essential to ensure that the action can be implemented in the African and Asian regions, and this is vital to counter the spread of the risk of, among others, Mpox spreading in the EU, therefore protecting the health of the people in the Union.

This action will therefore contribute to the monitoring of the ongoing Mpox global health crisis as determined by the WHO 'PHEIC', while also ensuring transversally the consolidation of capacities for other cross-border health threats working towards countering the spread of threats that are considered a priority by HERA. 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 198, point (f), of the Financial Regulation (EU, Euratom) 2024/2509.

The award of a direct grant is duly justified as the beneficiaries are the only organisations that have the necessary technical competence and degree of specialisation. The beneficiaries will receive an invitation to submit a proposal individually.

This action contributes to the horizontal policy priority aimed at fighting climate change.

The action supports the Union'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 (a), (b) and (j), of Regulation (EU) 2021/522

OBJECTIVES, SCOPE AND ACTIVITIES

The scope of this action is to develop regional wastewater surveillance guidance for Africa and Asia, and to support countries in the institutionalisation wastewater surveillance systems that are appropriate, cost-efficient and have public health impact.

Objectives include the development of technical capacity development for wastewater-related laboratories and bioinformatics; the support to national wastewater strategic planning through optimising cost-efficient system design for priority pathogens, facilitating regional convergence on guidance and standards, and enhancing data-for-decision-making to impact public health; increasing national capabilities and expertise related to wastewater surveillance.

This action will ensure synergies with other activities funded by the Commission linked to the Mpox outbreak and wastewater surveillance and genomic sequencing, such as "CP-g-23-22 Direct grant to support the Africa Pathogen Genomics Initiative (PGI)", of the 2023 EU4Health work Programme[35] and "CP-CA-24-94.1/2 Support strategies, capacity and data for global wastewater and environmental surveillance", of the 2024 EU4Health work programme[36].

EXPECTED RESULTS AND IMPACT

This action in coordination and synergy with other initiatives at Union level will increase global preparedness and response to the current Mpox international outbreak, as well as other cross-border health threats, ensuring continuation and expansion of the global sentinel system for wastewater surveillance.

This action is expected to:

a) strengthen wastewater surveillance against the Mpox outbreak;
b) strengthen the pathogen data analytics;
c) strengthen the network to support outbreak detection;
d) strengthen genomics capacities; and
e) reinforce and further validate wastewater surveillance as a tool for health crisis management, as well as for pandemic preparedness against cross-border health threats.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – CP-g-25-04/05	Q3-Q4/2025	Africa CDC and ASLM EUR 2 000 000 Duke-NUS (Asia PGI) EUR 2 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant in accordance with Article 198, paragraph 1, point (f), of Regulation (EU, Euratom) 2024/2509	HaDEA	Africa CDC, ASLM, Duke-NUS

35 2023 EU4Health Work Programme.
36 2024 EU4Health Work Programme.

CP-g-25-06 Direct grant to Member States' authorities for enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats (HERA)

POLICY CONTEXT

This action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies.

In order to ensure the comprehensive and sustainable implementation and integration of a national infrastructure support programme providing direct grants for strengthening whole genome sequencing ('WGS') and Reverse Transcription Polymerase Chain Reaction ('RT-PCR') in EU/EEA countries, there is a need to continue supporting Member States to expand their capacity to identify and characterise serious cross-border health threats using WGS and RT-PCR by complementing and extending the HERA Incubator national support programme launched in 2021, as well as the direct grants launched by HERA under the 2022 EU4Health work programme. This action will contribute to a more rapid, comprehensive and effective surveillance of infectious diseases. The capacity building is intended to increase Member States' and associated countries' capacity to respond to health threats but also to strengthen WGS and RT-PCR capacity in non-crisis time and is linked to HERA's work towards strengthening sequencing capacities (as was announced in the Commission Communication introducing HERA). This action will aim to support scaling up of PCR and sequencing capacities only in Member States and associated countries that were not able to receive support from previous grants in 2021[37] and 2022[38] and will be implemented in collaboration with the ECDC.

The setup of national public health WGS and RT-PCR infrastructure for public health microbiology purposes is a national responsibility, and EU/EEA countries are already at various stages of implementing these technologies for routine testing and characterisation. 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' and associated countries' public health authorities.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The main focus of this action is to support activities, to enhance and/or improve national public health[39] WGS and/or RT-PCR capacity. The activities may target public health laboratories at national, regional and/or local level, and should facilitate integration of genomics-based

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37 Specifically, the action launched under the HERA Incubator (ECDC) - EUR-Lex - 52021DC0078 - EN - EUR-Lex.

38 Namely, grants under the 2022 EU4Health work programme action CP-g-22-01.04 "Direct grants to Member States' authorities: enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats (HERA)", and/or (specifically) under the call EU4H-2022-DGA-MS-IBA-1.

39 Member-States and Associated Countries that received grants under the ECDC procedure Grant/2021/PHF/23776 and EU4H-2022-DGA-MS-IBA-1 will not be eligible under this action.

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

EXPECTED RESULTS AND IMPACT

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

a) in the short-term, contribution to the establishment of a sustainable, efficient and high capacity WGS and/or RT-PCR infrastructure for national public health microbiology;
b) in the short/medium-term, contribution to early detection and enhanced monitoring of health threats at the national and the EU/EEA levels;
c) in the medium/long-term, contribution to enhanced genomic-based infectious disease outbreak investigation capacities at regional, national and/or EU/EEA levels;
d) in the medium/long-term, contribution to enhanced routine genomic-based surveillance of infectious diseases at the regional, national and/or EU/EEA levels; and
e) in the long-term, contribution to enhanced preparedness to timely and efficiently address cross-border outbreaks of infectious diseases and pandemics in the future.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – CP-g-25-06	Q3-Q4/2025	EUR 5 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities not having participated in previous actions under the "HERA Incubator" or under action CP-g-22.01.04 of the 2022 EU4Health work programme

CP-g-25-07 Direct grants to Member States' authorities to implement HERA's training and exercise programme for management of medical countermeasures (HERA)

POLICY CONTEXT

HERA's training and exercise programme is comprehensive, covering all aspects linked to the development, production, procurement, stockpile and distribution of medical countermeasures ('MCMs'), supporting the development of preparedness, readiness and actual response capacities of Member States to respond to a cross-border health crisis. The training and exercise

programme will also support innovative policy developments by looking and sharing best practices as well as strengthen coordination and information sharing at Union level.

HERA's training and exercise programme is implemented through a variety of activities, some essentially aimed at strengthening individual capacities, like eLearning or thematic workshops, and others encouraging organisational developments and improvements, like simulation exercises and an exchange programme. The programme targets national, regional and local authorities in Member States' authorities working on health preparedness, readiness and response, in particular policymakers and planners with strategic and tactical responsibilities.

Following a phased implementation approach, that started with the organisation of thematic workshops, eLearning and simulation exercises, the Joint Action aims at implementing the exchange programme, including temporary exchange of experts, country visits and twinning activities.

Through this Joint Action, HERA's exchange programme builds on the wealth of expertise and experience existent in the Union, arising from a variety of health systems and of health crisis governance across the Union. It considers the need felt by Member States to improve inter-agency collaboration at national and Union levels. It will ensure knowledge transfer and exchange of best practices among public institutions and practitioners working across the MCM management cycle. This will strengthen institutional capacities and resilience, facilitate coordination, improve mutual understanding and enhance solidarity among Member States.

In addition, HERA's exchange programme will enhance international cooperation by facilitating exchanges and fostering connections between Member States and global partners working across the MCMs lifecycle.

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 also has a Union added value. 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 objective defined in Article 4, point (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The main goal of this Joint Action is to implement HERA's exchange programme, which aims to strengthen Member States' skills and knowledge along the MCM life cycle, closing the current gap between different levels of preparedness and response capacities. The exchange programme also has the following programmatic objectives:

- To strengthen the European and global network of public health professionals using state-of-the-art practices and methods, shared standards and policies along the MCM cycle.
- To facilitate innovative inter-disciplinary and multi-sectorial cooperation among different public institutes and organisations of the Member States, including the private sector where relevant.
- To support the sharing of best practices and lessons learned along the MCM cycle from past and ongoing cross-border health crises and simulation exercises among Member States, and eventual third countries and international organisations.

- To develop and support knowledge transfers and networking within and between different public health services, organisations and agencies of national authorities and crisis centres of Member States, encouraging cross border cooperation.

To achieve these objectives, this Joint Action provides a platform to share knowledge, best practices, lessons learned and innovative approaches between public health institutions of Member States. To the extent possible, these activities will be implemented in parallel and in coordination with remaining and ongoing training actions, like eLearning, workshops and simulation exercises (included in previous EU4Health work programmes).

The action will include the following activities:

- Short-term exchange of staff/experts from different Member States;
- Country visits to different Member States, including relevant sites, like laboratories, stockpile warehouses, crisis coordination centres or private sector (e.g. pharma companies);
- Twinning activities between institutions based on different Member States; and
- Dissemination and outreach activities.

EXPECTED RESULTS AND IMPACT

It is expected that the action will strengthen institutional capacities and resilience, facilitate coordination, improve mutual understanding and enhance solidarity among Member States. Positive impacts are expected on the overall MCM preparedness and response capacities of the country or region where the participant institutions are located. It is expected that the programme will foster the development and implementation of best practices, improve problem solving and innovation, lead to the harmonisation of policies and standards, and increased cooperation. The programme will also help to strengthen international relations between organisations and countries, facilitating mutual understanding, encouraging solidarity and thus, fostering cooperation.

Consequentially, in the mid and long term, it is expected that this exchange programme will contribute to reduce the differences across Europe in preparedness and response capacities regarding access to medical countermeasures needed to respond to cross border health threats, improve the overall capacity and capabilities of organisations, leading to improved performance and outcomes and create long-term collaboration and partnerships between organisations.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – CP-g-25-07	Q3-Q4/2025	EUR 2 947 923
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action) in	HaDEA	Member States' authorities

accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509		

CP-g-25-08 Direct grants to Member States' authorities for setting up a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union

POLICY CONTEXT

In the context of the Union's evolving policy landscape on animal and public health, action CP-g-22-04.01 from the 2022 EU4Health work programme[40], set to span its implementation phase from 2024 to 2026, represents a significant stride towards an integrated modern One Health approach in coordination with other actions carried out by the Union and ECDC on human health surveillance[41]. This initiative, having secured substantial engagement and financial commitment from pilot Member States, underscores a collaborative effort to enhance cross-border pathogen surveillance systems, intertwining human, animal, and environmental health dimensions by making use of the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) scientific expertise and joint risk assessment capabilities, also in the framework of the cross-agency One Health task force established in 2023.

Planning for the continuation of this action in the 2027-2028 period, it is imperative that this new action builds upon this foundation, further enhancing the Union's resilience against major zoonotic diseases (e.g. zoonotic avian influenza) and moving from a first phase with "pilot Member States" to an "all Member States" longer lasting action, while at the same time reducing the risk and losses due to discontinuation of the initiative.

Noting the wide consensus from Member States on the need to continue and expand on the current initiative, the forthcoming period 2027-2028 should aim to address gaps identified during the previous action and stabilising structural surveillance (e.g. zoonotic avian influenza), both based on Union legislative provisions and technical risk assessment by EFSA and ECDC and also by leveraging advancements in technology and integrated data analytics for more robust surveillance and response mechanisms. It will be crucial to continue fostering a high level of cooperation within Member States' competent authorities, among Member States and between Union agencies such as the EFSA and ECDC with the One Health mindset. This approach will not only enhance disease detection and management but will also contribute to the Union's overarching goal of safeguarding public and animal health and environmental integrity in a changing global landscape. In other terms foster the momentum for One Health operationalisation.

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.

40 2022 EU4Health Work Programme.

41 Based on the report on "Lessons learnt from COVID-19 surveillance and other epidemics on integrated and real-time of surveillance in the EU/EEA", on the Joint Action on Integrated surveillance, including the setting – up of human and animal health data integration (AWP 2021 - CP-g-02.1.1) and in cooperation with the Direct Grants to improve national surveillance systems (AWP 2023).

This action implements the EU4Health Programme's general objectives of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health (Article 3, point (b), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will enhance the detection, assessment, and communication of cross-border health threats from zoonotic diseases by fostering One Health surveillance focusing on animals and also the environment.

It will be supporting a surveillance framework for zoonotic diseases in animals and the environment for all Member States. This will involve substantial technical and financial means to support sample collection, testing data sharing and analysis of disease surveillance data while supporting Member States' implementation of Union legislation, in particular the Animal Health Law [42]

The action will, for the period 2027-2028, follow and build up on action CP-g-22-04.01 of the 2022 EU4Health work programme. The action will foster the framework of the One Health surveillance system, using as pillars the Union legislation, the collaboration with EFSA, in coordination with the ECDC and the Member States. The implementation will see more Member States using their upgraded surveillance systems, with a revised list of priority pathogens (including vector borne zoonoses) subject to surveillance, and, when needed, integrating innovative surveillance practices for animals and the environment, while promoting synergy with human health risk assessment. Where possible, synergies should be sought with the action supported under CP-g-25-02. This holistic approach will be underpinned by continuous collaboration with EFSA, in coordination with the ECDC.

Member States are expected to:

1. refine sample collection strategies and the national scope;
2. carry out the systematic collection and perform the needed diagnostic procedures;
3. foster genotyping and genomic surveillance for selected priority pathogens;
4. streamline national data management processes, from collection to sharing;
5. conduct preliminary assessments to pinpoint national priorities and risks within the One Health framework;
6. share data with EFSA and contributing to the annual re-evaluation of health risks, aiding in the surveillance system's fine-tuning.

This should allow for an iterative process, reviewed in year two, which will allow for the adjustment of surveillance priorities and methods based on EFSA and ECDC risk assessments in case similar actions are to be continued in the future.

EXPECTED RESULTS AND IMPACT

The activities will significantly enhance the One Health surveillance framework, leading to a more integrated and seamless monitoring system for priority zoonoses in animals and the environment across the Union, accession countries and selected neighbouring countries. By fostering closer collaboration on zoonotic diseases, it will enhance the Union surveillance

[42] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'); OJ L 84, 31.3.2016, p. 1–208.

system (e.g. highly pathogenic avian influenza, West Nile fever) for threats to human health with a One Health approach.

This action requires the delivery by each grant of the following specific mandatory deliverables: Member State' authorities, in alignment with the assessment conducted by EFSA, in coordination with the ECDC, and with the active participation of the Member States, will submit to EFSA the surveillance data collected in a defined format, at least on a yearly basis or more frequently.

Member State' authorities that will be awarded with a grant will need to submit to EFSA, during the implementation of the grant:

a) The detailed outcome of their surveillance activities by disease and by surveillance methodology; and
b) A dedicated summary of the national assessment across animal and public health and the environment in a One Health approach.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants - CP-g-25-08	Q4/2025	EUR 15 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States in accordance with Article 198, first paragraph, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

CP-g-25-09 Direct grants to EU Reference Laboratories (EURLs) to support their functioning in accordance with Regulation (EU) 2022/2371 on serious cross-border threats to health

POLICY CONTEXT

Article 15(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU[43] empowers the Commission to designate EU reference laboratories ('EURLs') in the area of public health or for specific areas of public health relevant for the implementation of this Regulation. The aim of these EURLs is to provide support to reference laboratories at the national level and 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.

[43] OJ L 314, 6.12.2022, p. 26.

Strengthening Europe's defences against cross-border health threats is essential to a high level of health security within the Union. Public health microbiology laboratories are a first line of defence against health threats from communicable diseases, including rising multi-drug resistance of human pathogens. Adequate laboratory capacity is therefore a critical component of preparedness as it allows for rapid detection of infectious diseases and identification of transmissible agents and is crucial for providing early warnings of epidemics in order to control them effectively[44]. Coordinated EU laboratory support thus strengthens preparedness, surveillance, crisis management and outbreak response capacities in the Member States, thereby representing an area with clear added value at Union level.

In their role as providers of this coordinated Union laboratory support, the EURLs for public health will be sharing best practices and supporting the modernisation and harmonisation of laboratory-based surveillance methods. They will also be strengthening laboratory capacities by providing technical support within the Union's disease-specific networks that are set up and coordinated by the European Centre for Disease Prevention and Control ('ECDC'). This will support the Member States to foster sufficient laboratory capacity at the national level, thus leading to enhanced preparedness to prevent, detect, and respond to disease threats. In addition, the EURLs should, through both individual activities and through the network of EURLs, seek cooperation and coordination with existing reference laboratories and networks at the international level, including with the WHO reference laboratories and/or collaborating centres. Tapping into work carried out by global initiatives and laboratories outside the Union will further strengthen the work of the EURLs and reinforce Union health security preparedness and response objectives.

Designated EURLs will become part of the network of EURLs that will be managed by the ECDC and that is formed in accordance with Article 15(3) of Regulation (EU) 2022/2371. The aim of this network is to foster coordination between the EURLs on issues such as standardisation and harmonisation of shared activities (including report templates for activities such as External Quality Assessments etc.), data and material transfer agreements, best practice exchanges etc.

The EURLs for public health are being gradually designated over a number of years[45]. This action supports the functioning of the next EURL(s) for public health to be designated based on the submission of successful applications under the Calls for Application(s) that will be published by DG SANTE in Q2 2025[46]. The grants will cover the costs of activities that will be carried out by these designated EURL(s).

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 designated EURLs, which solely have the responsibility to implement the action.

The policy priority of this action is strengthening the responsiveness of Member States to cope with serious cross-border threats to health and to enhance preparedness for future health emergencies. It implements the EU4Health Programme's general objective of protecting people

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44 https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-public-health-microbiology-strategy-2018-2022.pdf.

45 EU Reference Laboratories for public health - European Commission.

46 The purpose of the Calls for Application(s) is for the European Commission to invite laboratories in the EU/EEA to submit applications in view of their possible designation, via implementing act, as EURL in the specific field(s) defined by the Calls for Application(s) and in accordance with Article 15 of Regulation (EU) 2022/2371. Those EURLs are to be formally designated by an implementing act to be adopted by the Commission in line with Article 15(1) of Regulation (EU) 2022/2371.

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

Laboratories that are established Albania, Kosovo, North Macedonia, Serbia or Türkiye are eligible to participate in the projects as associated partner without funding in accordance with Article 13(1)(iii), (2) and (3) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The future EURL(s) shall provide support to the national laboratories that are part of the ECDC disease network(s) relevant to scope of the EURL(s). The EURL(s) will be integrated into and form an integral part of ECDC's existing networks and structures, and will, where relevant, have a coordination function for the implementation of laboratory support activities within 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; and
h) assistance to implement the Union laboratory and surveillance strategies.

The scope and mandatory activities of the future EURL(s) will be defined by the Calls for Application(s) to designate EURL(s) that will be published by DG SANTE in Q2 2025. The activities of this action must be aligned with what will be specified in the Calls for Application(s) to designate EURL(s), and the proposals submitted under the action must include all tasks and activities included in the corresponding successful application(s).

The action will cover the costs of activities that will be carried out by the designated EURL(s) that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with the EU4Health Programme[47].

As stipulated by Article 15(3) of Regulation (EU) 2022/2371, the designated EURL(s) shall cover cooperation and coordination with existing reference laboratories and networks, including the World Health Organization ('WHO') reference laboratories. The scope of the activities of the EU reference laboratories is thus not restricted to the Union or third countries associated to the EU4Health Programme, and international cooperation may be sought with laboratories based in Albania, Kosovo, North Macedonia, Serbia and Türkiye.

EXPECTED RESULTS AND IMPACT

This action will enable the designated EURL(s) for public health to carry out laboratory support tasks within the areas specified within Article 15 of Regulation (EU) 2022/2371, and thus contribute to its implementation. In particular, the expected results are the following:

- establishment of one or more EU reference laboratories for disease(s) / health issue(s) that are of priority at Union level and within the scope of Regulation (EU) 2022/2371;
- implementation of EU reference laboratory support activities for public health reference laboratories at the national level within these priority areas;

[47] Article 8(4) of Regulation (EU) 2021/522.

- contribution to the activities of the network of EURLs coordinated by ECDC.

Further results, including specific deliverables, are expected from the future designated EURL(s) and will be as defined in the Calls for Application(s) to designate EURL(s) in accordance with Article 15 of Regulation (EU) 2022/2371.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grants – CP-g-25-09	Q3/Q4 2025	EUR 6 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to designated EU reference laboratories for public health in accordance with Article 198, paragraph 1, point (d), of Regulation (EU, Euratom) 2024/2509	HaDEA	Designated EU reference laboratories

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1. RARE DISEASES

DP-g-25-10 Direct grant to Orphanet to support disease codification knowledge and information sharing

POLICY CONTEXT

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

An essential part of the European Reference Networks ('ERNs')[48] initiative is the possibility to integrate clinical cases in medical registries. This is only possible if a coherent and uniform coding system is widely used by all health care providers which, in the domain of rare diseases, is the existing orphacode system. This also aligns with the Commission's continued support to the European Platform on Rare Disease Registration (EU RD Platform), which copes with the fragmentation of rare disease patients' data in more than 600 registries across Europe.

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 198, point (f), of the Financial Regulation (EU, Euratom) 2024/2509. The award of a direct grant is duly justified as the beneficiary is the only organisations that have the necessary technical competence and degree of specialisation and is the sole entity capable of carrying out this action.

This action supports the establishment of a harmonised coding system for rare diseases. It implements the EU4Health Programme's general objective of strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (f), (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The proposed 3-year action will include the integration of Orphanet nomenclature and orphacodes as the main codification system for rare diseases in the IT systems of the ERNs and healthcare providers, and the continuous maintenance, update and improvement of the system based on scientific analysis of the state-of-the-art knowledge in the area of rare diseases.

EXPECTED RESULTS AND IMPACT

ERNs and Orphanet constitute a unique European framework dedicated to rare diseases with key complementary roles. ERNs have the clinical and scientific expertise on rare diseases and Orphanet has the expertise on databases, codification, and standardisation. The project is expected to enhance this complementary role and creating a synergic approach.

This action is expected to contribute to the harmonisation of the codification systems and thus enable to fill medical registries with data coming from the ERN clinical discussion system and

[48] European Reference Networks - European Commission.

potentially also from national systems. Quantity and quality of healthcare and research activities on rare diseases are expected to improve substantially.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grant – DP-g-25-10	Q3/2025	EUR 3 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant in accordance with Article 198 point (f), of Regulation (EU, Euratom) 2024/2509	HaDEA	Orphanet coordinating team- INSERM US14

3. CANCER, CARDIOVASCULAR AND OTHER NON-COMMUNICABLE DISEASES (CR/CV&NCD)

3.1. CANCER INITIATIVES

CR/CV&NCD-g-25-12 Call for proposals to pilot and implement cancer screening programmes for gastric cancer

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[49] in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. On 9 December 2022, a new Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening, was adopted[50]. It is the cornerstone of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan. It aims to ensure that the latest available scientific evidence is reflected, including an extension of screening to prostate, lung, and gastric cancers, based on further research. One of the main instruments to implement the Council Recommendation is the Joint Action EUCanScreen, action CR-g-23-38 of the 2023 EU4Health work programme. Gastric cancer is the tenth most frequent cancer in the Union, and the seventh leading cause of cancer deaths. The incidence is almost twice as high in men as in women, and across Member States, incidence and mortality vary four-fold. This is partially due to different prevalence of risk factors, such as infection with the bacterium *Helicobacter pylori*. The 2022 Council Recommendation therefore recommends screen-and-treat strategies for H. pylori, including implementation studies, in those countries or regions with high gastric cancer incidence and death rates, taking into account precancerous stomach lesions unrelated to H. pylori infections. Through action CR-g-22-09.03 of the 2022 EU4Health work programme, a first set of projects including pilot studies and further explorative work in the area of gastric cancer screening have been launched such as the project 'Towards gastric cancer screening implementation in the European Union' ('TOGAS'). Through the 2023 and 2024 EU4Health work programmes, preparatory work for the planned Commission Initiative on Gastric Cancer has been initiated, aiming to develop European guidelines and quality assurance schemes for gastric cancer screening and care. To build on this work, and to ensure further roll-out across the EU, further piloting activities and support to implementation at national level will be needed.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action will contribute to the implementation of gastric cancer screening programmes, in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes within national priorities, as called for in the 2022 Council Recommendation on cancer screening. The use of AI in ongoing (pilot) programmes shall be

[49] Council Recommendation of 2 December 2003 on cancer screening http://data.europa.eu/eli/reco/2003/878/oj.

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

assessed, and the potential use of AI, where feasible, further be explored. Potential synergies with the project stemming out of the "Call for proposals on advancing the adoption of artificial intelligence in health" (DI-g-24-76 of 2024 EU4Health work programme) shall be explored. The action may include the following activities:

- facilitating implementation research via new pilots and programme rollout initiatives through:
  - monitoring and assessment of on-going implementation studies;
  - defining needs for and planning of new implementation studies based on gap analyses, building on deliverables of the TOGAS project; supporting, coordinating and running implementation studies within Member States;
  - linking regional/national implementations studies within Member States to reduce duplication and human/financial resources as well as to increase study impact;
  - regular quality assessment and improvement of implementation research.
- collection and assessment of benefits/harms data and other data on outcomes, quality assurance and cost-effectiveness relating to gastric cancer screening programmes from the national level based on the established methods, infrastructure, and networks within the previous EU4Health Programme funded projects;
- linking relevant experts and representatives from European medical societies and patient organisations to ensure broad outreach to corresponding national partner societies and patient organisations;
- effective dissemination as well as bidirectional knowledge exchange with all Member States relating to gastric cancer screening;
- close collaboration with related projects, such as those covering lung and prostate cancer screening, and the Joint Action Implementation of cancer screening programmes ('EUCanScreen')[51] from the 2023 EU4Health work programme action CR-g-23-38; and
- close collaboration with the Commission's Joint Research Centre, and the alignment with the outputs of the planned Commission Initiative on Gastric Cancer; and
- exploration of the potential of AI in gastric cancer screening.

The following specific mandatory deliverables and/or milestones must be achieved:

- report on ongoing (pilot) programmes and implementation studies for gastric cancer screening in Member States;
- report on latest available evidence on benefits and harms, outcomes, quality assurance and cost-effectiveness of gastric cancer screening originating from the ongoing (pilot) programmes and implementation studies;
- establishment of network of gastric cancer screening experts and relevant representatives from European medical societies and patient organisations;
- launch of gastric cancer implementation studies, including at least one implementation study, or sub-topic within one study, on the use of AI where feasible;
- Inclusion of an equity perspective (how to reach underrepresented or vulnerable sub-populations);
- report on the potential and the actual use of AI in ongoing gastric cancer screening (pilot) programmes and implementation studies (both within and outside of the project); and
- report on how the project will build on results of previous relevant EU-funded projects (particularly TOGAS and Accelerating gastric cancer reduction in Europe through

[51] 2023 EU4Health Work Programme.

Helicobacter pylori eradication ('EUROHELICAN') of the 2021 EU4Health work programme, action DP/C-g-08.6.1[52]), on how the findings of the previous pilot activities have informed the new studies, and on how synergies with parallel actions and initiatives will be used particularly:

- parallel projects on lung and prostate cancer screening,
- Joint Action EUCanScreen, to ensure alignment with Member States' needs and priorities and to take into account findings generated through relevant work packages,
- upcoming work on the third EU Cancer Screening Monitoring Report, to ensure alignment on data collection and monitoring activities,
- and the planned Commission Initiative on Gastric Cancer Screening, to ensure alignment with development of European guidelines and quality assurance scheme.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- regularly updated reporting and gap analysis to guide Member States;
- enhanced knowledge on the current state and feasible and successful modalities of gastric cancer screening programmes, including the integration of new AI-based screening technologies to improve detection and reduce disparities across Member States;
- further roll-out of gastric cancer screening;
- further availability of gastric cancer screening programmes in relevant Member States based on European Guidelines, as available.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for Proposals – CR/CV&NCD -g-25-12	Q3-Q4/2025	EUR 3 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Public authorities, research organisation, civil society organisations, ERNs, academia and education establishments, hospitals, international organisations, networks in field of health

[52] 2021 EU4Health work programme.

CR/CV&NCD-g-25-13 Call for proposals to pilot and implement cancer screening programmes for lung cancer

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[53] in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. On 9 December 2022, a new Council Recommendation[54] on strengthening prevention through early detection: A new EU approach on cancer screening was adopted. It is the cornerstone of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan. It aims to ensure that the latest available scientific evidence is reflected, including an extension of screening to prostate, lung, and gastric cancers, based on further research. Lung cancer is the second most diagnosed cancer in men, and the third in women. It is the leading cause of cancer death for men, and the second for women. Lung cancer mortality and five-year-survival rates vary significantly across the Union. The Council Recommendation encourages exploring the feasibility and effectiveness of lung cancer screening programmes with low-dose computed tomography, starting with individuals at high risk such as heavy smokers and ex-smokers, also taking into account primary and secondary prevention approaches such as smoking cessation. Artificial Intelligence based solutions and approaches can help roll-out lung cancer screening programmes in the Member States, however the approach needs to be scientifically sound and supported by scientific evidence. Through action CR-g-22-09.02 of the 2022 EU4Health work programme, a first set of projects including pilot studies and further explorative work in the area of lung cancer screening, such as 'Strengthening the screening of lung cancer in Europe' ('SOLACE') has been launched. Through the 2023 EU4Health work programme, preparatory work for the planned Commission Initiative on Lung Cancer has been initiated, to develop European guidelines and quality assurance schemes for lung cancer screening and care. Under the Digital Europe programme, Cancer Image Europe platform is deployed which supports collaborative multi-centric studies on AI in cancer. To build on this work, and to ensure further roll-out of lung cancer screening across the Member States, further piloting activities and support to implementation at national level will be needed.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action will contribute to the implementation of lung cancer screening programmes, to enhance early detection and programme efficiency. The gradual and appropriate planning, piloting, and roll-out of the screening programs will align with national priorities and the latest scientific advancements as called for in the 2022 Council Recommendation on cancer screening. The use of AI in ongoing (pilot) programmes shall be assessed, and the potential use of AI, where feasible, further be explored. Synergies with actions implementing the European

[53] Council Recommendation of 2 December 2003 on cancer screening http://data.europa.eu/eli/reco/2003/878/oj.

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

Cancer Imaging Initiative, in particular the Cancer Image Europe platform, shall be explored. Potential synergies with the project stemming out of the "Call for proposals on advancing the adoption of artificial intelligence in health" (DI-g-24-76 from the 2024 EU4Health Work Programme) shall be explored. The action may include the following activities:

- facilitating implementation research via new pilots and rollout initiatives through:
  - monitoring and assessment of on-going implementation studies;
  - defining needs for and planning of new implementation studies based on gap analyses, building on deliverables of the SOLACE project;
  - supporting, coordinating and running implementation studies within Member States;
  - linking regional/national implementations studies within Member States to reduce duplication and human/financial resources as well as to increase study impact;
  - regular quality assessment and improvement of implementation research.
- facilitating aggregation and analysis of the cancer imaging datasets, allowing cross-border multi-centric cooperation on AI studies, including research and development of replicable AI algorithms for lung cancer screening and for strengthening the evidence base for AI uptake in lung cancer screening programmes;
- collection and assessment of benefits/harms data and other data on outcomes, quality assurance and cost-effectiveness relating to lung cancer screening programmes from the national level based on the established methods, infrastructure and networks within the previous EU4Health Programme funded projects;
- linking relevant experts and representatives from European medical societies and patient organisations to ensure broad outreach to corresponding national partner societies and patient organisations;
- effective dissemination as well as bidirectional knowledge exchange with all Member States and relevant candidate countries relating to lung cancer screening;
- close collaboration with related projects, such as those covering prostate and gastric cancer screening, and the Joint Action Implementation of cancer screening programmes ('EUCanScreen') from the 2023 EU4Health work programme action CR-g-23-38;
- close collaboration and alignment with the Commission's Joint Research Centre and the outputs of the planned Commission Initiative on Lung Cancer;
- exploration of the potential of artificial intelligence ('AI') in lung cancer screening in synergy with the activities under the European Cancer Imaging Initiative.

The following specific mandatory **deliverables and/or milestones** must be achieved:

- report on ongoing (pilot) programmes and implementation studies for lung cancer screening in Member States;
- report on latest available evidence on benefits and harms, outcomes, quality assurance and cost-effectiveness of lung cancer screening originating from the ongoing (pilot) programmes and implementation studies;
- establishment of a network of lung cancer screening experts and relevant representatives from European medical societies and patient organisations;
- launch of lung cancer screening implementation studies, including at least one implementation study, or sub-topic within one study, on the use of AI;
- inclusion of smoking cessation support activities in the pilot studies;
- inclusion of an equity perspective (how to reach underrepresented or vulnerable sub-populations);

- report on the potential and the actual use of AI in ongoing lung cancer screening (pilot) programmes and implementation studies (both within and outside of the project);
- report on how the project will build on results of previous relevant EU-funded projects (particularly SOLACE), on how the findings of the previous pilot activities have informed the new studies, and on how synergies with parallel actions and initiatives will be used particularly:
  - parallel projects on prostate and gastric cancer screening,
  - Joint Action EUCanScreen, to ensure alignment with Member States' needs and priorities and to take into account findings generated through relevant work packages,
  - European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, to foster the AI uptake in lung cancer screening,
  - upcoming work on the third EU Cancer Screening Monitoring Report, to ensure alignment on data collection and monitoring activities,
  - and the planned Commission Initiative on Lung Cancer Screening, to ensure alignment with development of European guidelines and quality assurance scheme.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- regularly updated reporting and gap analysis to guide Member States;
- enhanced knowledge on the current state of play and feasible and successful modalities of lung cancer screening programmes, including the integration of new AI-based screening technologies to improve detection and reduce disparities across Member States;
- further roll-out of lung cancer screening;
- further availability of lung cancer screening programmes across the Member States.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – CR/CV&NCD -g-25-13	Q3-Q4/2025	EUR 7 440 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Public authorities, research organisation, civil society organisations, ERNs, academia and education establishments, hospitals, international organisations, networks in field of health

CR/CV&NCD-g-25-14 Call for proposals to pilot and implement cancer screening programmes for prostate cancer

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[55] in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. On 9 December 2022, a new Council Recommendation[56] on strengthening prevention through early detection: A new EU approach on cancer screening was adopted. It is the cornerstone of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan. It aims to ensure that the latest available scientific evidence is reflected, including an extension of screening to prostate, lung, and gastric cancers, based on further research. Prostate cancer is the most common cancer in men, and the third cause of cancer death. Mortality rates vary threefold across the Union. The 2022 Council Recommendation recommends, in view of the significant amount of ongoing opportunistic screening, to evaluate the feasibility and effectiveness of the implementation of organised programmes on the basis of prostate-specific antigen ('PSA') testing for men, in combination with additional magnetic resonance imaging ('MRI') scanning as a follow-up test. Artificial Intelligence based solutions and approaches can help roll-out prostate cancer screening programmes in the Member States, however the approach needs to be scientifically sound and supported by scientific evidence. Through action CR-g-22-09.01 of the 2022 EU4Health work programme, a first set of projects including pilot studies and further explorative work in the area of prostate cancer screening, such as 'Prostate cancer awareness and initiative for screening in the European Union' ('PRAISE-U') has been launched. Through the 2023 EU4Health work programme, preparatory work for the Commission Initiative on Prostate Cancer has been initiated, to develop European guidelines and quality assurance schemes for prostate cancer screening and care. Under the Digital Europe programme, Cancer Image Europe platform is deployed which supports collaborative multi-centric studies on AI in cancer. To build on this work, and to ensure further roll-out of prostate cancer screening across the Union, further piloting activities and support to implementation at national level will be needed.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action will contribute to the implementation of prostate cancer screening programmes, in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes within national priorities, as called for in the 2022 Council Recommendation and upcoming European Guidelines on cancer screening. The use of AI in ongoing (pilot) programmes shall be assessed, and the potential use of AI, where feasible, further be explored. Synergies with actions implementing the European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, shall be explored. Potential synergies

[55] Council Recommendation of 2 December 2003 on cancer screening http://data.europa.eu/eli/reco/2003/878/oj.

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

with the project stemming out of the "Call for proposals on advancing the adoption of artificial intelligence in health" (DI-g-24-76 from 2024 EU4Health work programme) shall be explored. The action may include the following activities:

- facilitating implementation research via new pilots and programme rollout initiatives through:
  - monitoring and assessment of on-going implementation studies;
  - defining needs for and planning of new implementation studies based on gap analyses, building on deliverables of the PRAISE-U project;
  - supporting, coordinating and running implementation studies within Member States;
  - linking regional/national implementations studies within Member States to reduce duplication and human/financial resources as well as to increase study impact;
  - regular quality assessment and improvement of implementation research.
- facilitating aggregation and analysis of the prostate cancer imaging datasets, allowing cross-border multi-centric cooperation on AI studies, including research and development of replicable AI algorithms for prostate cancer screening and for strengthening the evidence base for AI uptake in prostate cancer screening programmes
- collection and assessment of benefits/harms data and other data on outcomes, quality assurance and cost-effectiveness relating to prostate cancer screening programmes from the national level based on the established methods, infrastructure and networks within the previous EU4Health Programme funded projects.
- linking relevant experts and representatives from European medical societies and patient organisations to ensure broad outreach to corresponding national partner societies and patient organisations.
- effective dissemination as well as bidirectional knowledge exchange with all Member States and relevant candidate countries relating to prostate cancer screening.
- close collaboration with related projects, such as those covering lung and gastric cancer screening, and the Joint Action Implementation of cancer screening programmes ('EUCanScreen') from the 2023 EU4Health work programme action CR-g-23-38.
- close collaboration with the Commission's Joint Research Centre, and the planned Commission Initiative on Prostate Cancer.
- exploration of the potential of artificial intelligence (AI) in prostate cancer screening to detect prostate cancer at an earlier stage and reduce disparities in access to diagnosis among high-risk populations in synergy with the activities under the European Cancer Imaging Initiative.

The following specific **mandatory deliverables and/or milestones** must be achieved:

- report on ongoing (pilot) programmes and implementation studies for prostate cancer screening in Member States;
- report on latest available evidence on benefits and harms, outcomes, quality assurance and cost-effectiveness of prostate cancer screening;
- establishment of a network of prostate cancer screening experts and relevant representatives from European medical societies and patient organisations;
- launch of prostate cancer implementation studies, including at least one implementation study, or sub-topic within one study, on the use of AI where feasible;
- inclusion of an equity perspective (how to reach underrepresented or vulnerable sub-populations);

- report on the potential and the actual use of AI in ongoing prostate cancer screening (pilot) programmes and implementation studies (both within and outside of the project); and
- report on how the project will build on results of previous relevant EU-funded projects (particularly PRAISE-U), on how the findings of the previous pilot activities have informed the new studies, and on how synergies with parallel actions and initiatives will be used particularly:
  - parallel projects on lung and gastric cancer screening,
  - Joint Action EUCanScreen, to ensure alignment with Member States' needs and priorities and to take into account findings generated through relevant work packages,
  - European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, to foster AI uptake in prostate cancer screening,
  - planned work on the third EU Cancer Screening Monitoring Report, to ensure alignment on data collection and monitoring activities,
  - planned Commission Initiative on Prostate Cancer Screening, to ensure alignment with development of European guidelines and quality assurance scheme.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- regularly updated reporting and gap analysis to guide Member States;
- enhanced knowledge on the current state of play and feasible and successful modalities of prostate cancer screening programmes, including the integration of new AI-based screening technologies to improve detection and reduce disparities across Member States;
- further roll-out of prostate cancer screening;
- further availability of prostate cancer screening programmes across the Union based on European Guidelines, as available.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for Proposals – CR/CV&NCD-g-25-14	Q3-Q4/2025	EUR 7 440 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Public authorities, research organisation, civil society organisations, ERNs, academia and education establishments, hospitals, international organisations, networks in field of health

CR/CV&NCD-g-25-15 Direct grants to Member States' authorities to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA)

POLICY CONTEXT

The Commission is committed to ensuring that patients receive the best possible protection from the undesired effects of ionising radiation, while fully benefiting from the advantages it offers in diagnosing and treating cancer and other diseases. Based on the requirements of Council Directive 2013/59/Euratom[57] laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, there remains room for improvement of the quality and safety of medical radiation applications.

In February 2021, the Commission adopted the Strategic Agenda for Medical Ionising Radiation Applications ('SAMIRA') Action Plan[58], as a contribution to Europe's Beating Cancer Plan. One of the SAMIRA's primary objectives is to support the implementation of high standards for quality and safety of medical applications of ionising radiation into Member States' health systems. This is done with the help of a Steering Group on Quality and Safety of Medical Applications of Ionising Radiation ('SGQS') comprising Member State health and radiation protection authorities. The proposed Joint Action follows the SGQS advice on the need for Union support for developing closer cooperation and co-ordinated actions between Member States.

A series of SAMIRA-related topical activities being implemented between 2021-2025 are producing evidence and guidance, such as guidance for clinical audit of medical radiological procedures and implementation of requirements related to therapeutic radiopharmaceuticals, and the need for a sustainable framework for their implementation in Member States has emerged. The joint action will build on the SAMIRA preparatory action CR-g-23-44-03 under the 2023 EU4Health work programme, preparatory activities to support implementation of quality and safety of medical ionising radiation applications ('JA PrISMA').

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

OBJECTIVES, SCOPE AND ACTIVITIES

The objective is to ensure tangible and sustainable improvements in quality and safety of medical radiological procedures in Member States by supporting the co-ordinated implementation of good practice developed in the context of SAMIRA in the national health systems. The vision is to build on the evidence, lessons and recommendations from the SAMIRA projects and translate them into practical implementation in several countries simultaneously. There are many common concepts, objectives and solutions to Member States in the fields of radiation protection and health care, but there are also national adaptations that make each country unique. For that reason, a broad network of organisations with similar interests will serve as a source of experience and inspiration to develop necessary tools

[57] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom; OJ L 13, 17.1.2014, p. 1–73.

[58] SWD(2021) 14 final on the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA).

adaptable to circumstances in each Member States. The Joint Action will serve, among other purposes, as a forum to exchange good practices between Member States, on topics such as upgrades of medical equipment stocks and reporting of patient radiation doses.

Activities in the SAMIRA Joint Action will include among others in-person meetings and workshops, to enable effective networking and communication between organisations (hospitals, professional societies, authorities) in different Member States. Also, implementation of best practices previously developed in the SAMIRA Action Plan can be evaluated in a wider group of stakeholders in participating Member States, which will require site visits. An example is the need to practically review implementation of patient radiation monitoring requirements or clinical audits of medical radiological procedures.

For particular topics and project results to be implemented in Member States, it may be necessary to have professional (outsourced) services, such as the use of a digital collaboration platform, or development of software or databases, or education and training of for example clinical staff and auditors.

The following specific **mandatory deliverables and/or milestones** must be achieved:

- best practice guidance and working procedures for clinical auditing of computed tomography (CT) referrals to improve justification of diagnostic radiology;
- development of new/update of existing working procedures for incident reporting in radiotherapy, diagnostic/interventional radiology;
- development of new/update of existing working procedures for recording and monitoring of patient radiation dose;
- development and dissemination of practical guidelines on optimisation of paediatric radiation protection;
- development of guidelines for optimisation of image-guided radiotherapy;
- implementation of the requirements of Council Directive 2013/59/Euratom Basic Safety Standards Directive[59] related to optimisation and dosimetry in radiopharmaceutical cancer therapy.

EXPECTED RESULTS AND IMPACT

Having achieved efficient collaboration and communication, the involved network will work towards development of evidence and 'best practice' guidance, and the implementation of guidance and recommendations developed by the SAMIRA initiative, such as:

- improvement of justification of CT scans and other relevant radiological imaging modalities;
- improvement of justification and optimisation of paediatric radiological imaging;
- implementation of Council Directive 2013/59/Euratom Basic Safety Standards Directive requirements related to patient radiation dose monitoring;
- adoption of the radiological optimisation tools, including AI assisted tools, such as those developed under European projects;
- improvement of the radiation incident reporting and learning systems;
- full data coverage in staff registers and application of staffing calculation methods;

[59] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom; OJ L 13, 17.1.2014, p. 1–73.

- revision of education and training and continuing professional development programmes for medical professions employed in radiology, radiotherapy and nuclear medicine;
- establishment and regular reporting on medical radiation quality and safety key performance indicators.

The output of these activities may include working procedures, templates, new or updated best practice guidance documents, installation of IT tools relevant to implementation measures mentioned above, etc. Dissemination, learning and information sharing activities should be planned, including regular online meetings as well as periodic in-person meetings should be held to agree on next steps and discuss results.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grant - CR/CV&NCD-g-25-15	Q4/2025	EUR 11 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

CR/CV&NCD-g-25-16 A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation

POLICY CONTEXT

In the Union, non-communicable diseases ('NCDs') are responsible for approximately 86% of all deaths. placing a significant burden on citizens' lives, health systems, and economies.

Cardiovascular diseases ('CVDs') are the single largest contributor to the NCD burden, causing over 3.9 million deaths annually in Europe and more than 6 million new cases each year in the Union alone. Often coexisting with or driven by comorbid diseases like cancer, cancer treatments, or conditions such as diabetes, obesity, metabolic disease, and hypertension, they represent not only a clinical endpoint but also a sentinel for wider chronic disease and morbidity risk.

In this context, cardiovascular health becomes a proxy for broader metabolic and chronic health, shaped by genetic predispositions, social and environmental determinants, and modifiable risk factors, such as unhealthy diet linked poor nutrition, and the high intake of salt, sugar and saturated fat or highly processed food. Preserving cardiovascular health means intervening early and intelligently to prevent disease escalation across the spectrum of interrelated NCDs.

Yet, despite well-established clinical knowledge on risk factors, most CVDs and related conditions remain undetected until late stages, often when irreversible damage has occurred. The current fragmentation of health data, coupled with limited deployment of Artificial Intelligence ('AI') solutions, hampers timely, targeted, and scalable interventions.

CVDs represent a strategic area for Union action — not only due to their epidemiological weight, but also because of their relatively high predictability and preventability. Advances in health data infrastructure and AI create new opportunities to detect early signals, identify individuals at risk, enable personalised prevention and treatment, and empower citizens to better manage their condition.

Rapid progress in AI including in medical imaging, predictive analytics, and personalised interventions, has demonstrated strong potential to transform the early detection and prevention of NCDs, including cancer, and now **cardiovascular and related metabolic diseases**. However, the deployment and scale-up of AI tools remain limited across Member States, due to challenges in **data access and quality**, **limited clinical integration**, and a lack of **continuous performance evaluation** in real-world healthcare settings.

The Union is actively promoting trustworthy AI in healthcare with a variety of initiatives such as building a regulatory framework conducive for innovation (e.g. Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space, Regulation (EU) 2024/1689 of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (AI Act), Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, and Regulation (EU) 2019/881 of the European Parliament and of the Council on ENISA and on cybersecurity certification (Cybersecurity Act)) as well as targeted innovation promotion measures such as the GenAIEU initiative and AI Factories. Dedicated Union funding programmes (e.g. EU4Health Programme, Digital Europe Programme, Horizon Europe) support the development and deployment of AI solutions in healthcare in the Union.

Integration of genomic insights into AI models and tools could help discern the complex impact of multiple genetic mutations on an individual's predisposition to CVDs and related NCDs, contributing to mitigating the risk of an early onset and severe course of the disease by triggering preventive measures. Moreover, in-silico modelling and virtual human twin technologies could offer relevant synergetic opportunities. AI has the potential to improve the efficiency and effectiveness of healthcare systems, enhance patient outcomes, and reduce healthcare costs.

Despite rapid innovation, many AI solutions still lack real-world validation, remain under-deployed and are even less frequently scaled-up across the Union's diverse healthcare systems. The challenges are multifaceted, including the limited access to good quality and representative data, insufficient skills, low acceptance, and clinical or organisation workflows that are not ready for the integration of such AI tools. Fragmented regulatory frameworks and the lack of continuous clinical performance evaluation further hamper the ability to ensure that AI systems perform equally well in diverse healthcare environments and are appropriately deployed into clinical practice.

The European Health Data Space ('EHDS')[60] facilitates secure and privacy-preserving access to health data across the Union, supporting research and innovation such as the development of AI-powered cardiovascular applications. By streamlining access to representative health data from Europe's population, the EHDS can enable the creation of more accurate and effective AI

[60] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en.

models and support the scaling up of AI solutions across the Union. As part of the Commission broader efforts to promote AI in healthcare (as described in the section “Synergies/links with other EU programmes”) initiatives such as the 1+ Million Genomes, the European Virtual Human Twins, and Cancer Image Europe can provide valuable synergies. Integration of genomic insights into AI models and tools could help discern the complex impact of multiple genetic mutations on an individual's predisposition to CVDs, contributing to mitigating the risk of early onset and severe progression of the disease by triggering preventive measures. Moreover, in-silico modelling and virtual human twin technologies could offer relevant synergetic opportunities. This initiative aims to ensure comprehensive AI adoption in medicine, balancing technological innovation, clinical practice, and regulatory frameworks to deliver high-quality, safe, and effective care.

This initiative aims to enable responsible and widespread adoption of mature AI applications for cardiovascular health and related non-communicable diseases in clinical practice, by addressing deployment conditions, generating real-world evidence, and promoting high-quality, standards-based implementation. It seeks to create the conditions for scaling-up well-performing AI models in line with EU values, clinical needs, and data protection requirements**.** The facilitation of an accelerated and regulated uptake of AI solutions offers strategic opportunities to advance these broader goals and to help to reduce the burden of cardiovascular diseases, which remain a leading cause of death and disability in the Union. This action does not aim at developing new AI technologies, but at supporting the conditions for their responsible and scalable adoption in healthcare systems. It focuses on testing mature AI tools in real-world settings, producing evidence-based deployment protocols, and overcoming barriers to safe, effective and equitable integration of such tools in clinical workflows.

This action will build on synergies with the ‘Advancing the adoption of AI in health’ action DI-g-24-76 under 2024 EU4Health work programme, ensuring alignment in objectives and leveraging findings, particularly regarding good deployment practices for AI in healthcare. The synergies with relevant actions, including on genomics, funded under EU4Health, Digital Europe and Horizon Europe programmes are key to enhancing the collective efforts to promote AI in healthcare.

It supports the development, validation and adoption of AI solutions in healthcare based on European data, in compliance with EU regulatory frameworks. This strengthens the Union’s capacity to rely on trustworthy, high-performing AI solutions tailored to its healthcare needs, and reduces dependency on non-EU technologies and datasets.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This initiative aims to leverage AI and health data to accelerate the early detection, prediction, personalised prevention, integrated management and rehabilitation of CVDs and related NCDs, including rare and complex forms.

The initiative is structured around two complementary and mutually reinforcing objectives.

Together, they aim to lay the foundations for a European model of AI-enabled cardiovascular and comorbid chronic disease care, grounded in high-quality health data and real-world validated solutions.

The initiative should take into account the distinctive features of different population groups with regards to NCDs; such as socio-economic differences, gender differences etc.

Objective 1 — Leveraging Health Data for AI Applications in Cardiovascular and Related Chronic Diseases

The first objective is to structure, federate, and enable access to high-quality health data across the Union to support the development, training, validation, and deployment of AI tools focused on cardiovascular diseases and related non-communicable diseases (such as diabetes and obesity).

This will align with and prepare for the future application the EHDS, which provides the regulatory and technical framework to enable the secure, privacy preserving, and interoperable secondary use of health data across Member States.

To achieve this objective, the initiative will support the following activities:

1. **Federating High-Quality and Diverse Health Datasets Across the EU**: The action will support the identification, connection, and federation of **large-scale datasets** relevant to cardiovascular diseases and related chronic conditions. Particular attention will be paid to ensuring **data quality, completeness, diversity, and representativeness**, including the inclusion of data from underrepresented populations and healthcare contexts. This federation will enhance the ability to train robust, generalisable AI models across borders. The solutions proffered by the Collaborating Health Information European Framework ('CHIEF') initiative taken into account and implemented were appropriate.
2. **Defining Minimum Technical Specifications for Cardiovascular Datasets**: Building on existing Union and international standards, the initiative will support the **definition of a core set of technical specifications** for datasets to be used in AI development and validation. These specifications will include **cardiovascular phenotypes**, **genomic and biometric markers**, as well as **metadata standards and labelling schemes**. This will ensure consistency, comparability, and high-quality input data for AI algorithms.
3. **Supporting Targeted Data Collection Aligned with These Specifications**: To address current gaps in data availability or standardisation, especially in some Member States or healthcare systems, the action will promote **targeted efforts to collect or harmonise data** in line with the agreed specifications. This includes support to public health institutions, research infrastructures, and data holders to strengthen **data completeness and interoperability** across the Union.
4. **Establishing a Federated Data Infrastructure under the EHDS Framework**: The initiative will support the **development of a federated (distributed) repository model**, leveraging the European Health Data Space. This infrastructure will enable **secure, privacy-preserving and decentralised access** to health datasets for the **training, validation, benchmarking, and testing** of AI models. It will promote the **cross-border use of data without centralisation**, in full respect of Union rules on data protection, cybersecurity, and ethical use.

Objective 2 — Deploying AI Solutions for Risk Prediction, Prevention, Treatments, and Personalised Care

The second objective is to identify, validate, and scale up mature AI applications capable of improving the risk prediction, early detection, personalised prevention, treatment, and rehabilitation of cardiovascular and related chronic diseases.

The action should also include AI models that integrate diverse health data sources—such as electronic health records, wearable devices, and socioeconomic and commercial determinants of health—to generate individualised risk assessments and care recommendations.

To achieve this, the initiative will support the following activities:

1. **Develop a Strategic Roadmap for AI in Cardiovascular and Chronic Disease Care:** to guide the safe, effective, and inclusive adoption of AI solutions. It will outline key milestones, enablers, stakeholder roles, and barriers across the innovation-to-adoption pathway. This roadmap should build on relevant Union initiatives, including JACARDI, the 1+ Million Genomes Initiative, and the European Virtual Human Twin Initiative.
2. **Map and Select Mature AI Solutions for Real-World Piloting**: The initiative will identify AI tools with strong evidence base and readiness for implementation/scale up, focusing on:
    - Early detection (e.g. imaging analysis, wearables, multimodal data),
    - Personalised risk prediction (e.g. EHRs, socioeconomic and commercial determinants),
    - Tailored prevention (e.g. individualised screening, lifestyle interventions, chronic disease management).
3. **Pilot AI Solutions in Real-World Healthcare Settings**: Selected AI tools will be piloted in diverse environments—such as hospitals, community clinics, general practice, telehealth platforms, and public health systems—across the Union. Particular attention will be paid to clinical integration, scalability, and inclusivity. Interdisciplinary collaboration involving clinicians, AI developers, engineers, patients, and regulators will be essential.
4. **Design a Blueprint and Deployment Protocols for Large-Scale Integration:** Based on lessons from the pilots, the initiative will develop a blueprint and a set of deployment protocols to guide the scale-up of validated solutions. These will address technical integration and interoperability, clinical validation and performance monitoring, regulatory alignment and organisational readiness, training, patient engagement, and data governance.
5. **Produce Evidence-Based Guidelines and Organisational Recommendations**: The initiative will support the development of:
    - Clinical guidelines for the safe and effective use of AI in cardiovascular and chronic disease care, including guidance on interpretation, validation, and data quality;
    - Operational guidance for healthcare institutions, to support adoption at the organisational level, including infrastructure, workflows, and governance.
6. **Evaluate Impact and Foster Stakeholder Engagement:** AI solutions will be assessed for feasibility, user acceptance, clinical effectiveness, cost-efficiency, and ethical compliance (equity, privacy, transparency). Broad stakeholder engagement will be promoted to ensure relevance, trust, and uptake.

For all listed activities, a particular spotlight should be on AI models that **support individual cardiovascular risk prediction, prevention and treatment**.

EXPECTED RESULTS AND IMPACT

This initiative is expected to generate **tangible, scalable results** supporting the adoption of **AI-driven personalised care** for cardiovascular diseases and related non-communicable

conditions, while laying the **foundations of a trusted European data ecosystem** for health innovation.

Expected results – Data dimension

- **Creation of a large-scale, federated, high-quality dataset** for cardiovascular and metabolic diseases, aligned with the EHDS framework. This dataset will be representative, inclusive, and interoperable, and will enable the development, training and benchmarking of AI tools across borders.
- **Definition and uptake of minimum technical specifications** for cardiovascular datasets, including structured phenotypes, genetic and biometric markers, and metadata quality labelling.

Expected results – AI adoption dimension

- **Validated AI solutions**: A portfolio of AI tools will be piloted in real-world clinical settings, with demonstrated effectiveness in early detection, risk prediction, and personalised prevention of cardiovascular and related chronic diseases.
- **Deployment frameworks**: The initiative will produce practical guidelines and protocols to facilitate the integration and scale-up of AI applications across diverse healthcare systems. These will cover governance, interoperability, clinician training, patient engagement, and continuous performance monitoring.
- **Strategic guidance**: The publication of a **roadmap** and a **blueprint for large-scale integration** will inform health authorities, hospitals, and policymakers on how to responsibly and sustainably adopt AI tools, supporting informed decisions at national and Union levels.
- **Robust evidence base**: The project will generate comparative data on safety, performance (e.g. sensitivity, specificity, cost-effectiveness), usability and acceptability, informing both clinical practice and health policy.

Anticipated impact

- **Improved health outcomes**: Earlier diagnosis and more targeted prevention of NCDs, leading to reduced disease progression, complications, and avoidable mortality.
- **Greater equity**: Enhanced access to personalised diagnostics and AI-supported care pathways, especially in underserved regions or Member States with limited innovation capacity.
- **Efficiency and sustainability of health systems**: Better use of resources through predictive and preventive approaches, reducing the burden of chronic conditions on healthcare infrastructures.
- **Trust in European health AI**: By ensuring compliance with data protection, safety, and transparency standards, the initiative will foster trust in the responsible use of AI for health in line with the AI Act and EHDS Regulation. It will also support the uptake — and where relevant, the development — of specifications and standards foreseen under both frameworks, notably for interoperability, risk management and data governance.

Expected Union contribution: The Commission estimates that a Union contribution of EUR 20 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for Proposals – CR/CV&NCD-g-25-16	Q3-Q4/2025	EUR 20 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Networks of experts such as European Reference Networks (ERNs), European societies or other recognised EU-level collaborations in cardiology and public health Civil Society Organisations: Associations, Foundations and NGOs. Enterprises (incl. social enterprises and not for profit) in the field of public health Private entities (for profit/not for profit) Public authorities, such as ministries of health, regional health agencies, or health insurance bodies actively engaged in public health initiatives.) Established networks in the field of public health, such as European or transnational organisations recognised under Union law

3.2. LIFELONG PREVENTION FOR A HEALTHY LIFE, INCLUDING THROUGH EARLY DETECTION AND SCREENING - FOCUS ON CARDIOVASCULAR DISEASES

CR/CV&NCD-g-25-17 Direct grants to Member States' authorities to support lifelong prevention for a healthy life, including through screening, with focus on cardiovascular diseases

POLICY CONTEXT

Europe is facing a huge challenge related to its ageing population and the impact on society. A significant rise in life expectancy has been observed across Member States in the last decades. Improvements in living and social conditions, advancements in health care and general economic progress have all led to an increasing number of European citizens living longer lives. As a result, many of them have to manage multiple morbidities at the same time.

Europe's population is ageing and that comes with consequences for health services and policy, including on healthy longevity, due to the rising burden of non-communicable diseases, such as cardiovascular diseases and neurodegenerative disorders[61]. In fact, non-communicable diseases, such as cardiovascular diseases and diabetes, represent 80% of the health burden. This burden can best and most efficiently be addressed via prevention, through which 70% of it can be avoided. Therefore, it is essential to support Member States and citizens in this area as it is the core of the health and financial burden of disease. Prevention efforts must therefore be ramped up through the entire lifespan, starting with pregnancy and early childhood and reaching out to the elderly supporting healthy longevity. Cardiovascular diseases remain the leading cause of premature death in the Union and were estimated to cost the Union EUR 282 billion in 2021 [62]. More than 6 million new cases of cardiovascular diseases are diagnosed in the Union each year and almost 49 million people are living with the disease. It is estimated that around 32 million people in the Union are living with diabetes, with 90% of cases being type 2 diabetes which is largely preventable. These figures underscore the substantial burden that cardiovascular diseases place on individuals, health systems and economies within the Union. The data highlights the need for continued focus on prevention, early diagnosis, treatment and care within the Union.

Although the OECD[63] has made a strong case for increasing spending on health promotion and disease prevention measures as it is cost-effective, health spending remains overwhelmingly focused on curative care, with only 3% of total health spending going toward prevention on average. (2017, 2022 OECD "Health at a Glance" reports)[64].

The "State of Health- synthesis report"[65] highlights that a multi-sectoral approach is needed to tackle health inequalities and that investments in public health, disease prevention and health systems should remain a key priority in the medium term. The 2024 OECD "Health at a Glance"

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61 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on The European Health Union: acting together for people's health (COM(2024)206 final).

62 European Heart Journal, Volume 44, Issue 45, 1 December 2023, Pages 4752–4767.

63 How much do OECD countries spend on prevention?", OECD Health Working Papers, No. 101, OECD Publishing, Paris, https://doi.org/10.1787/f19e803c-en.

64 Health at a Glance: Europe - European Commission (europa.eu).

65 State_2023_synthesis-report_en.pdf (europa.eu).

report[66] recommends prioritising prevention throughout the life course and empowering individuals to manage their own health.

A comprehensive, cross-cutting, multi-sectoral and lifelong approach to preventive health is needed to support individuals' potential for healthy longevity. Such an approach should be evidenced-based and include health promotion and disease prevention strategies targeting in particular children and young people, with initiatives aimed at improving nutrition, physical activity, and mental well-being. This will also include early detection, as appropriate, improving integrated patient pathways, enhancing the quality of life of patients, and addressing multimorbidity and specific disease-related challenges. Prevention should also focus on population-wide measures and not unfairly place all the burden on the individual choices. Therefore, a cross-cutting approach to healthy longevity and lifelong prevention should go beyond public health and strongly include other key policy areas.

This approach aims to reduce the burden of non-communicable diseases, such as cardiovascular diseases, diabetes, and neurodegenerative disorders, and related risk factors, and to promote healthy lifestyles at every stage of life. This is key to adding healthy life years and must consider the determinants of health, including commercial and socio-economic determinants.

The objective of a healthy lifespan for all and of a healthier ageing population brings opportunities and challenges for Member States that will only grow in importance in the future. Broad ranging policy and legislative changes at Union and national level are needed to react to both long-standing and new and emerging challenges in an ageing population. Union support can be decisive to achieve these purposes. In 2023, the Expert Group on Public Health ('PHEG') identified the main priorities and actions on public health challenges for the period 2024-2026. Health promotion and socio-economic determinants of health were the most relevant, followed by mental health, cancer and the prevention of non-communicable diseases in general, and cardiovascular diseases in particular. Working on vaccine-preventable diseases and vaccination was also identified as a priority. The priorities of the PHEG focused on mental health, and on health promotion and prevention of non-communicable diseases in 2024. The focus of the PHEG's in 2025 will be on healthy longevity, lifelong prevention of diseases including cardiovascular diseases, vaccine-preventable diseases, and vaccination, as well as specific communicable diseases, such as TB, HIV/AIDS and hepatitis. The Commission will support the collection of best and promising practices via the EU Best Practices Portal.

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 also has a Union added value. It supports the implementation of "Healthier Together – EU Non-communicable diseases initiative" and the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare (i.e. to step up the work on preventive health and the work on cardiovascular diseases and continued implementation of and Europe's Beating Cancer plan) and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

[66] OECD/European Commission (2024), *Health at a Glance: Europe 2024: State of Health in the EU Cycle*, OECD Publishing, Paris, https://doi.org/10.1787/b3704e14-en.

This joint action aims to reduce the burden of disease and improve healthy longevity, supporting and empowering citizens to lead healthier lives throughout the entire lifespan, including an active and autonomous elderly population. This will be achieved by means of a comprehensive, multi-sectoral and lifelong prevention approach to healthy longevity that supports the creation of effective opportunities to improve health for all and to reduce health inequalities in the Union.

The joint action will build on existing actions deriving from the 'Healthier Together' – EU Non-communicable diseases initiative, the joint actions JACARDI and PreventNCD and the policy priorities of the Union and Member States as identified under the priority-setting exercise of the PHEG. It will support Member States in translating the policy priorities into concrete actions. The mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare, highlights and renews the Commission's work on preventive health. By ensuring a comprehensive approach to health promotion and disease prevention across the life course, the Commission will support Member States to lighten the load on healthcare systems and support healthy longevity. The focus of the Commission's work on prevention will include cardiovascular diseases, mental health, neurodegenerative disorders, autism and other non-communicable diseases, The mission letter draws attention to risk factors, such as tobacco, and the need to protect people in the EU, especially young people from the harmful effects of tobacco and related products in an ever-changing market landscape.

The joint action will support Member States in strengthening efforts on the prevention, early detection and management of cardiovascular diseases, as the leading cause of premature death in the Union.

The joint action will support the Union's policy development and legislative work on tobacco control, including in the context of the Europe's Beating Cancer Plan. The joint action will thus support the Europe's Beating Cancer Plan's objective of improving health promotion and health literacy, reinforcing measures to control tobacco and nicotine consumption, in particular among younger populations and with a focus on emerging products.

Activities will aim to support Member States in the preparation and implementation of prevention policies and programmes including early detection and screening, together with Member States, with a special focus on tackling major non-communicable diseases, with a focus on cardiovascular diseases. This will include:

- identification of concrete actions to support national policies by means of a structured approach addressing gaps and challenges with specific and efficient public health tools;
- implementation of coordinated actions and approaches for health promotion and disease prevention at national or Union level targeting the key public health challenges, focusing on cardiovascular diseases;
- development of common tools and instruments, such as plans, evidence-based policies and concrete actions, including innovative and ambitious practices, to address key challenges in a comprehensive, prevention-oriented manner;
- development, piloting and implementation of approaches promoting the equitable access to treatment and care of non-communicable diseases, notably cardiovascular diseases.

More specific activities will include:

a) development, piloting and implementation of population-level interventions, innovative and cost-effective approaches and research results to address the gaps in the prevention of non-communicable diseases across the Member States, with a focus on

cardiovascular diseases, as the leading cause of mortality and the key cause of ill-health and disability in the EU, as well as diabetes and obesity, which are closely linked.

b) development and piloting of guidance considering the blueprint developed for cancer screening, on the early detection and management of specific non-communicable diseases in line with the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare to support Member States in strengthening early detection, diagnosis and management of diseases.
c) development, piloting and implementation of ambitious and innovative public health interventions, with a specific focus on children and young people on tackling risk factors such as the use of tobacco and emerging products, alcohol, diet, nutrition and physical activity, with the main aim of creating better conditions for healthy longevity.
d) development and piloting of approaches that support the use of efficient health tools for the prevention and management of non-communicable diseases and their risk factors, including unhealthy diets, food with high fat, sugar and/or salt content, and sedentary behaviour.
e) transfer of best practices and piloting of promising practices on the prevention of non-communicable diseases, in particular cardiovascular diseases, including those collected via the EU Best Practices Portal[67], the WHO and OECD.
f) activities supporting the development of policies and implementation of actions that support tackling public health challenges, including new and emerging ones, in the Union. These activities will be developed in alignment with the Union's priorities on health.

The activities will include a horizontal dimension that focuses on the specific needs of vulnerable groups (e.g. children and young people, refugees/migrants, displaced people from Ukraine having temporary protection, Roma, drug users, prisoners), older persons, persons with chronic conditions.

The activities should also include an equity dimension and aim at reducing inequalities.

This joint action will build on the activities of the Joint Action JAPreventNCD[68] and Joint Action CARdiovascular diseases and DIabetes ('JACARDI')[69].

EXPECTED RESULTS AND IMPACT

Through this joint action, Member States will collaborate in their efforts to reach the health-related UN Sustainable Development Goals, in particular goal 3 to ensure healthy lives and promote well-being for all at all ages, and 2025 WHO targets for non-communicable diseases as well as new and emerging challenges of an ageing population, regardless of gender, socio-economic status and place of residence.

The Expert Group on Public Health ("PHEG") identified priorities for action (2024-2026) that include health promotion and prevention of non-communicable, cancer, mental health, and healthy longevity, lifelong prevention, vaccination and vaccine-preventable diseases and tackling infectious diseases.

The joint action will support the Member States in identifying concrete actions for a structured and coordinated prevention-oriented approach to addressing the key public health challenges.

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67 https://webgate.ec.europa.eu/dyna/bp-portal/.

68 2022 EU4Health work programme, EU4H-2022-JA-02 (CR-g-22-08.01) Direct grants to Member States' authorities: Cancer and other NCDs prevention – action on health determinants.

69 2022 EU4Health work programme, EU4H-2022-JA-03 (DP-g-22-06.03) Direct grants to Member States' authorities: prevention of NCDs –cardiovascular diseases and diabetes.

It will also contribute to support the implementation of the Europe's Beating Cancer Plan, in particular its objective of improving health promotion and health literacy, achieving a tobacco-free Europe.

The expected short-term impact would be an increased number of public health interventions being scaled up in Member States and improvements in health promotion and disease prevention. This joint action is also expected to support the scaling up of actions, programmes and policies that promote healthy lifespans as well as healthy and active ageing from early stages of life and empower older generations.

The following specific mandatory **deliverables and/or milestones** must be achieved:

- development, piloting and implementation of evidence-based policy actions and population level interventions, aligned with the Union's and Member States' priorities on health, to address key challenges in a comprehensive, prevention-oriented manner.
- development of common objectives and tools for the prevention and management of non-communicable diseases, with a specific focus on cardiovascular diseases, and related risk factors, including obesity.
- development of guidance to improve health literacy in the general population and targeted groups, in particular on cardiovascular diseases and related risk factors.
- development, piloting and implementation of an EU-level protocol on the early detection and screening of at-risk groups and development of interventions to support the prevention and management of cardiovascular diseases.
- identification and transfer of best practices and piloting of promising practices, including those collected via the EU Best Practice Portal, on lifelong prevention, healthy longevity, and the reduction of key risk factors (e.g. tobacco, alcohol, nutrition, physical activity).
- development and piloting of innovative approaches that aim to promote healthy longevity.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grants – CR/CV&NCD-g-25- 17	Q4/2025	EUR 5 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

CR/CV&NCD-g-25-18 Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases

POLICY CONTEXT

Europe is facing a huge challenge related to its ageing population and the impact on society. A significant rise in life expectancy has been observed across Member States in the last decades. Improvements in living and social conditions, advancements in health care and general economic progress have all led to an increasing number of European citizens living longer lives. As a result, many of them have to manage multiple morbidities at the same time.

Europe's population is ageing and that comes with consequences for health services and policy, including on healthy longevity, due to the rising burden of non-communicable diseases, such as cardiovascular diseases and neurodegenerative disorders[70]. In fact, non-communicable diseases, such as cardiovascular diseases and diabetes, represent 80% of the health burden. This burden can best and most efficiently be addressed via prevention, through which 70% of it can be avoided. Therefore, it is essential to support Member States and citizens in this area as it is the core of the health and financial burden of disease. Prevention efforts must therefore be ramped up through the entire lifespan, starting with pregnancy and early childhood and reaching out to the elderly supporting healthy longevity. Cardiovascular diseases remain the leading cause of premature death in the Union and were estimated to cost the Union EUR 282 billion in 2021[71]. More than 6 million new cases of cardiovascular diseases are diagnosed in the EU each year and almost 49 million people are living with the disease. It is estimated that around 32 million people in the Union are living with diabetes, with 90% of cases being type 2 diabetes which is largely preventable. These figures underscore the substantial burden that cardiovascular diseases place on individuals, health systems and economies within the Union. The data highlights the need for continued focus on prevention, early diagnosis, treatment and care within the Union.

Although the OECD[72] has made a strong case for increasing spending on health promotion and disease prevention measures as it is cost-effective, health spending remains overwhelmingly focused on curative care, with only 3% of total health spending going toward prevention on average. (2017, 2022 OECD "Health at a Glance" reports)[73].

The State of Health 2023 synthesis report[74] highlights that a multi-sectoral approach is needed to tackle health inequalities and that investments in public health, disease prevention and health systems should remain a key priority in the medium term. The 2024 OECD "Health at a Glance" report[75] recommends prioritising prevention throughout the life course and empowering individuals to manage their own health.

A comprehensive, cross-cutting, multi-sectoral and lifelong prevention approach to healthy longevity, that is evidence-based, is needed to support individuals' potential for healthy longevity. Such an approach includes health promotion and disease prevention strategies targeting in particular children and young people, with initiatives aimed at improving nutrition,

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70 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on The European Health Union: acting together for people's health (COM(2024)206 final).

71 European Heart Journal, Volume 44, Issue 45, 1 December 2023, Pages 4752–4767.

72 How much do OECD countries spend on prevention?", OECD Health Working Papers, No. 101, OECD Publishing, Paris, https://doi.org/10.1787/f19e803c-en.

73 Health at a Glance: Europe - European Commission (europa.eu).

74 State_2023_synthesis-report_en.pdf (europa.eu).

75 Health at a Glance: Europe 2024 - European Commission.

physical activity, and mental well-being. This will also include early detection, as appropriate, improving integrated patient pathways, enhancing the quality of life of patients, and addressing multimorbidity and specific disease-related challenges. Prevention should also focus on systemic and population-wide measures and not unfairly place all the burden on individual choices. Therefore, a cross-cutting approach to healthy longevity and lifelong prevention should go beyond public health and strongly include other key policy areas such as environment, housing, employment, etc.

This approach aims to reduce the burden of non-communicable diseases, such as cardiovascular diseases, diabetes, and neurodegenerative disorders, and related risk factors, and to promote healthy lifestyles at every stage of life. This is key to adding healthy life years and must consider the determinants of health, including commercial, environmental and socio-economic determinants.

The objective of a healthy lifespan for all and of a healthier ageing population brings opportunities and challenges for Member States that will only grow in importance in the future. Broad ranging policy and legislative changes at Union and national level are needed to react to both long-standing and new and emerging challenges in an ageing population. Union supports can be decisive to achieve these purposes. The Expert Group on Public Health (PHEG) identified the main priorities and actions on public health challenges for the period 2024-2026. Health promotion and socio-economic determinants of health were considered to be the most relevant, followed by mental health, cancer and the prevention of non-communicable diseases in general, and cardiovascular diseases in particular. Working on vaccine-preventable diseases and vaccination was also identified as a priority. The priorities of the PHEG focused on mental health, and on health promotion and prevention of non-communicable diseases in 2024. The focus of the PHEG in 2025 will be on healthy longevity, lifelong prevention of diseases, including cardiovascular diseases, vaccine-preventable diseases, and vaccination, as well as specific communicable diseases, such as TB, HIV/AIDS and hepatitis. The Commission will support the collection of best and promising practices via the EU Best Practices Portal.

This action supports the "Healthier Together – EU Non-communicable diseases initiative"and Europe's Beating Cancer plan and implements the EU4Health Programme's general objective to improve and foster health in the Union and to strengthen health systems by improving their resilience and resource efficiency (Article 3, point (a), of Regulation (EU) 2021/522), through the specific objective defined in Article 4, point (a), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to contribute to reducing the burden of non-communicable diseases, including cancer, and their risk factors across the lifespan, supporting Member States' actions. The action targets:

1. lifelong prevention of non-communicable diseases, notably cardiovascular diseases and diabetes (targeting all age groups, with a particular focus on children and adolescents, and vulnerable groups);
2. active and healthy ageing, empowering older generations;
3. reducing the use and exposure to tobacco and related products, with a focus on young people's access to emerging tobacco and nicotine products;
4. reducing harmful alcohol consumption, in particular in young people and vulnerable groups;
5. the promotion of healthy diets and physical to improve health;

6. reducing the impact on mental wellbeing of social media and excessive screen time with a focus on children and young people.

The activities will include:

- capacity-building for stakeholders to develop and pilot community-level, coordinated and innovative outreach and awareness actions to support the prevention of non-communicable diseases and relevant risk factors (tobacco, alcohol, nutrition and physical activity, etc);
- activities to improve health literacy targeting vulnerable groups;
- development and piloting of tools and instruments to address the lifelong prevention of non-communicable diseases;
- development and piloting of innovative approaches to reduce the health risks associated with the use of tobacco and alcohol, in particular in vulnerable groups;
- piloting of actions at community level on tackling risk factors for non-communicable diseases, including unhealthy diets and physical inactivity;
- development and piloting of ambitious and innovative public health interventions on tackling risk factors such as tobacco, alcohol, and second-hand exposure to smoke and aerosols from traditional tobacco and emerging products.

This action is linked to and should support relevant actions by the Member States in the joint action (CR/CV&NCD-g-25-17) Lifelong prevention for a healthy life, including through screening – focus on cardiovascular diseases.

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

Supports priorities for action identified by Expert Group on Public Health and the EU4Health Steering Group (22nd May 2023). The Expert Group on Public Health identified priorities for action (2024-2026) that include health promotion and prevention of NCDs, cancer, mental health, and healthy longevity, lifelong prevention, vaccination and vaccine-preventable diseases and tackling infectious diseases.

EXPECTED RESULTS AND IMPACT

This action will implement projects on health promotion, lifelong prevention of NCDs, including cancer, and aim for healthy diets, physical activity, and healthy and active ageing. It will also build on the priorities set by the Expert Group on Public Health in the area of prevention.

This action is expected to result in the piloting of population-level interventions, awareness-raising campaigns, capacity-building activities, and support for patient groups and organisations representing vulnerable groups.

This action is expected to support the efforts of Member States in addressing the challenges of an ageing population by strengthening lifelong prevention of NCDs, including cancer and cardiovascular diseases.

The short-term impact will be an increased number of public health interventions being scaled up in Member States, improvements in health promotion, prevention of NCDs, including cancer and their risk factors.

The following specific mandatory **deliverables and/or milestones** must be achieved:

- targeted awareness campaigns, which can include events, to build capacity among stakeholders with the aim of preventing non-communicable diseases and their risk factors;
- capacity-building events to improve health literacy targeting vulnerable groups;
- piloting of best and promising practices collected via the EU Best Practice Portal;
- development and piloting of community-level actions to address lifelong prevention of non-communicable diseases and related risk factors.

These activities must include a focus on vulnerable groups of the population.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for proposals – CR/CV&NCD-g-25-18	Q3/2025	EUR 2 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs; Civil Society Organisations: Associations, Foundations, NGOs

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

4.1. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND STRATEGY

HS-g-25-19 Direct grants to Member States' authorities to support the implementation of a common standard for medical product identification and AI capabilities across Member States

POLICY CONTEXT

Using harmonised and structured data – IDentification of Medicinal Products ('ISO IDMP') in human medicinal products is a necessity for interoperability across systems and a level playing ground with regards to having up to date and adequate information on medical products, use, availability and developments across the Union.

This is also required by the 2010 Pharmacovigilance legislation and more particularly Article 57(2) of Regulation (EC) No 726/2004[76]. EMA created a proprietary exchange format that needs to be replaced by ISO IDMP. As a next step, a significant update to comply with ISO IDMP standards was due to be completed by July 2016, as required by Commission Implementing Regulation (EU) No 520/2012[77]. A respective provision is in the Commission's proposals for a new pharmaceutical legislation, currently being negotiated by the co-legislators.

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 also has a Union added value. It will contribute to the implementation of the Pharmaceutical Strategy for Europe[78] and the revised pharmaceutical legislation, which is one of the priorities outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare.

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

Legal entities from Liechtenstein are eligible to participate in the project as associated partners without funding in accordance with Article 13(1)(iii), (2) and (3) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

National Competent Authorities ('NCAs') have started the work to implement ISO IDMP with the Horizon 2020 UNICOM project that lasting from December 2019 until November 2023. NCAs play a pivotal role being the non-biased and relevant providers of data for use of other actors in the e-Health and other ecosystems. Trusted data is also requested by patient organisations. The Union's pharmaceutical legislation applies to all EEA countries, including Liechtenstein, and they are part of the European medicines regulatory network as the Union acquis on medicinal products has EEA relevance. It is thus in the Union's interest to involve

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76 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

77 Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ L 159, 20.6.2012, p. 5).

78 Pharmaceutical Strategy for Europe (COM(2020) 761 final).

the EEA countries in this joint action with the aim of harmonising implementation of the Union pharmaceutical acquis. As EEA country without association to the EU4Health Programme, Liechtenstein can participate in this joint action only on a self-funded basis.

The objective of this project is to:

- allow ex-UNICOM NCAs and other EU/EEA and associated countries' NCAs to support other regulators to enhance their IT systems and processes towards compliance and interoperability;
- strengthen data exchange with e-Health authorities and EMA for national and EU/EEA and associated countries' use-cases;
- explore AI tools to support data mapping, quality controls and standardisation;
- set up a proper governance structure by:
  - developing and/or upgrading IT systems and data repositories;
  - continuing training and stakeholder engagement initiatives to build the necessary skills and consensus for effective and practical implementation of ISO-IDMP and the integration of EMA's Substance, Product, Organisation and Referential services;
  - bringing national regulators and e-Health authorities together to support a harmonised approach to medicines data processes and management.

EXPECTED RESULTS AND IMPACT

The expected results and impact are to:

- Achieve interoperability and availability across participating NCAs of trusted data related to regulatory processes of medicinal products, including data on the composition of a medicinal product and to uniquely identify a medicinal product. This outcome will be supported by the development of an NCA specific IDMP maturity model establishing a baseline to continuously measure the progress of the IMDP maturity among the participating partners.
- Support the participants in their digital transformation by providing e.g., educational material, training workshops. This will also promote collaboration and knowledge-sharing initiatives in the context of data quality management (and standardisation) using AI and potentially other tools among competent authorities and fostering co-development of initiatives. In line with the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare, this action will contribute to the uptake of AI in the lifecycle of medicines.
- Support ongoing/future initiatives in the EMA/HMA[79] Multi-annual AI Workplan that relate to topics within the scope of this joint action. This will ensure collaboration, alignment and complementarity among initiatives and avoid duplication of efforts.
- Increase the efficiency and effectiveness of regulatory processes, with a reduction of administrative burden by building up the foundation to utilise established common services from EMA.
- The mapping and knowledge-sharing with regard to relevant AI based tools in this joint action would also lead to a reduction of administrative burden and increase of data consistency by semantic validation of structured and non-structured information.
- Advance semantic and then technical interoperability, the data and digital transformation of the European Medicines Regulatory Network together with eHealth organisations will be further stimulated.

[79] Heads of Medicines Agencies.

- Identify use cases upon project start. Focus on electronic data exchange, utilising shared repositories, advancing national or cross-border eHealth scenarios, supporting data driven decision making to deliver a strong foundation for the Union's healthcare sectors, aligning with the goals of the European Health Data Space initiatives.
- Provide an interoperable foundation for any further innovation, research (including big data and AI) and a better management of availability of medicines shortages in alignment with the forthcoming new pharmaceutical legislation.
- The actions above are expected to reduce the authorisation time and increase access to medicinal products in all Member States. This is particularly relevant for innovative products and products addressing diseases creating a high burden for patients like cancers.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – HS-g-25-19	Q3-Q4/2025	EUR 9 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities, including medicines national competent authorities and e-Health authorities.

HS-g-25-20 Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database

POLICY CONTEXT

Pricing and reimbursement decisions influence access to cost-effective and affordable medicines. The Pharmaceutical Strategy for Europe notes that the Commission will foster transparency of price information to help Member States take better pricing and reimbursement decisions. It also commits to support mutual learning between national authorities, including on coverage of pharmaceutical costs and price increase criteria. The Draghi Report on the future of European competitiveness[80] highlighted the need for coordinated actions on pricing and reimbursement of medicines, including through databases such as the European Integrated Price Information Database ('EURIPID').

Contributing to these objectives, EURIPID is a voluntary non-profit collaboration of the Union's pricing and reimbursement authorities, sharing information on pharmaceutical pricing policies and prices of medicinal products.

[80] The future of European competitiveness, Part A | A competitiveness strategy for Europe and The future of European competitiveness, Part B | In-depth analysis and recommendations.

The recent OECD Health Working Paper co-funded by the Commission, on exploring the feasibility of monitoring access to medicines[81] concluded that whilst affordable access is a policy priority, systematic monitoring of its various dimensions is lacking and leveraging data captured in existing platforms such as EURIPID could aid systematic data collection and analysis.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, 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 (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The scope of this action is to develop through the EURIPID database:

a) a "pricing and reimbursement ('P&R') tracker", including national information on early access schemes; P&R applications, status, decision; and P&R criteria or conditions (general and product-specific);
b) access dashboards, building on OECD indicators, including on availability (e.g., coverage status, time-to-reimbursement), affordability (e.g., cost of treatment), accessibility (e.g., consumption/uptake);
c) an annual trend analysis report of access to medicines in the Union;
d) solutions that can facilitate data sharing with EURIPID, such as automatization using application programming interface and machine-machine interaction with each Member State;
e) reinforced interoperability of EURIPID with other existing databases (e.g. the European Shortages Medicine Platform, Substance, Product, Organisation and Referential master data, Product Management Service, etc.) and integrating data assets in the European Health Data Space.

The objectives are to:

a) measure and increase understanding of patient access to medicines in the Union;
b) increase the quality of the database, in terms of timely/correct data delivery;
c) expand the scope of the EURIPID members (to all the Member States) and data;
d) leverage usefulness of the data beyond external reference pricing purposes.

EXPECTED RESULTS AND IMPACT

In the short term, this action will provide EURIPID members with a better overview of access, P&R measures and decisions across the Member States.

In the longer term, it is expected to support mutual learning between national authorities and help the Member States in taking better pricing and reimbursement decisions, with a view to improve access, availability, and affordability of medicines. This is in line with the recommendations in the Draghi Report on the future of European competitiveness, and with the priority to ensure supply of affordable medicines, as outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare.

The proposed "pricing and reimbursement ('P&R') tracker" and access dashboard will allow improved monitoring of patients' access to medicines across the Union, including for cancer treatments. Having this data available prior to the application of the proposed pharmaceutical

[81] Exploring the feasibility of monitoring access to novel medicines: a pilot study in EU Member States, OECD 2023.

reform, will serve to measure the baseline and subsequently the impact of the proposed measures that aim to increase access to medicines across the Union, including for cancer treatments.

This action builds on action HS-g-22-17.01 of the 2022 EU4Health work programme[82], Call for proposals to develop early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases, therefore it is crucial that it is launched timely to ensure continuation of EURIPID functioning.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for proposals – HS-g-25-20	Q3/2025	EUR 750 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Authorities competent in the domain of pricing and reimbursement of medicines from the Member States being members of EURIPID

82 2022 EU4Health Work Programme.

HS-g-25-21 Direct grants to Member States' authorities on quality of medicines and implementation of the pharmaceutical legislation and the Pharmaceutical Strategy for Europe

POLICY CONTEXT

This action will contribute to the implementation of the future new pharmaceutical legislation (currently the legislative proposals are under negotiation by the co-legislators), the implementation of Article 111 of Directive 2001/83/EC[83] and the Pharmaceutical Strategy for Europe[84]. Also relevant are the international Mutual Recognition Agreements of the Union and Union cooperation with third countries that require concerted and continuous cooperation between the national Competent Authorities of the 30 EU/EEA countries, Compliance Group of the Good Manufacturing and Distribution Practice Inspectors Working Group ('GMDP IWG'), the GMDP IWG, the EMA and the Commission.

Over the past years, the Compliance Group of the GMDP IWG established – in cooperation with the EMA – the Joint Audit Programme to ensure consistency of implementation of Good Manufacturing Practice ('GMP') standards and a harmonised approach within EU/EEA countries s in line with the Compilation of Union Procedures on Inspections, and mutual recognition of inspection results. The programme was well maintained over the past years and proved its effectiveness e.g., in the establishment and maintenance of Mutual Recognition Agreements with the United States, Switzerland, Australia, Japan, New Zealand, and Trade Agreements with Canada and Israel.

In this policy context, the action will support the Commission's policy priority to implement the Pharmaceutical Strategy for Europe and will anticipate implementation of the new pharmaceutical legislation as it concerns the enhancement of compliance with GMP and Good Distribution Practices ('GDP') and the Compilation of Union Procedures that ensures patients' and animals' access to high-quality safe and effective medicines.

This joint action will give support to Union authorities to implement the Union pharmaceutical acquis and strengthen its implementation by strengthening the GMP and GDP inspections and Joint Audit Programme ('JAP') audit capacity that will help guarantee that high quality and effective medicines reach patients and animals (thereby observing Union environmental standards). It is notably key for improving patients' access to innovative cancer medicines.

This joint action builds on the 2021 EU4Health work programme action HS-g-18.2.1 Direct grants to Member States' authorities: to promote quality of medicines and to increase cooperation between the Member States and between the Union and third countries through trainings, joint audits, reassessments and inspections on GMP and GDP. Implementation of international Mutual Recognition Agreements on pharmaceutical GMP with the United States, Switzerland, Australia, Japan, New Zealand, Trade Agreements with Canada, Israel, the UK, and possible cooperation with other third countries, therefore it is crucial that it is launched timely to ensure continuity of activities related to quality of medicines.

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83 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 L 311, 28/11/2001, p. 67).

84 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pharmaceutical Strategy for Europe (COM/2020/761 final).

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 also has a Union added value. It will, among other things, contribute to the implementation of the Pharmaceutical Strategy for Europe. It implements the EU4Health Programme's general objective of strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (g), (h) and (i), of Regulation (EU) 2021/522.

Legal entities from Liechtenstein, as EEA country without association to the EU4Health Programme, are eligible to participate in the projects a**s** partner without funding in accordance with Article 13(1)(iii), (2) and (3) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

Due to the need to increase activities targeting all Member States and EEA competent authorities for human medicines, the overall objective of this action is to foster joint efforts in harmonising inspection and audit trainings including capacity improvement (e.g., increasing the number of qualified JAP auditors), and to support the Joint Audit Programme. All EEA countries, including Liechtenstein, are part of the Union inspections network, thus it is in the Union interest to involve them in this joint action with the aim to harmonise implementation of the Union pharma acquis. As EEA country without association to the EU4Health Programme, Liechtenstein can participate in this joint action only on a self-funded basis.

Considering the importance of the JAP, all Member States' experts should be given the opportunity to participate as auditors in the programme to further strengthen the EU medicines regulatory network and to ensure the harmonised oversight of the quality of medicinal products. Financial support should be offered to the Member States and eligible EEA countries, except Liechtenstein that can only participate on a self-funded basis, for carrying out JAP audits to enhance the sustainability of the inspectorates (audits are time and resource intensive).

Regarding the training of GMP inspectors, the goals regarding harmonisation and qualification should be developed in coherence with the EU Network Training Centre ('EU NTC') of the European Medicines Agency and need to cater for all the training needs of the Member States and the authorities of eligible EEA countries, including Liechtenstein that can only participate on a self-funded basis, incorporating cooperation with other international organisations (e.g. PIC/S).

The EU NTC will facilitate sharing of knowledge and strengthening of capacity within the European Medicines Regulatory Network, facilitating the development of the Network's capabilities, making best use of available resources, and supporting the quality and efficiency of operations.

The actions will also contribute to the strengthening of the capacity of the National Competent Authorities' audit and GMP inspections system, while investing in training of the auditors/inspectors. It will also include the development of GDP guidelines, as well as the development of a dedicated GDP training course. These actions will thus positively influence the sustainability of each EU National Competent Authority, and the EU inspectors' Network as a whole, while guaranteeing good quality medicines.

EXPECTED RESULTS AND IMPACT

The expected results and impact are to:

a) strengthen the regulatory network and ensure notably equivalent GMP and GDP regulatory compliance programmes;
b) maintain and foster the establishment of equal and harmonised standards for inspectors training and qualification throughout the EU/EEA;
c) support the Compliance Group of GMDP IWG and ensure a harmonised and independent approach for reviewing JAP audit reports and reinforcing the trust and reliance between Member States and with Union strategic Mutual Recognition Agreement partners;
d) continue the smooth introduction of GDPs to the JAP. It will be the basis to harmonise implementation and compliance of GDP inspection standards throughout EU/EEA countries, including Liechtenstein that can only participate on a self-funded basis, for the benefit of the security of the single market and of the legal supply chain ensuring good quality medicines for EU/EEA patients and animals.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grants – HS-g-25-21	Q4/2025	EUR 2 300 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

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

HS-g-25-22 Direct grant to EU Reference Laboratories for the Union contribution on *in vitro* diagnostic medical devices

POLICY CONTEXT

The implementation of Regulation (EU) 2017/745[85] and Regulation (EU) 2017/746[86] is a priority for the Commission, as highlighted in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare, the Council Conclusions on the Future of the European Health Union of June 2024[87] and several debates in the Employment, Social Policy, Health and Consumer Affairs Council configuration (the 'EPSCO Council'), the last one in December 2024.

EU reference laboratories ('EURLs') are a crucial type of scientific body in the diagnostics sector as laid out in Regulation (EU) 2017/746. The Commission has already designated some EURLs and may designate further EURLs in the future to ensure that laboratories are designated for all relevant categories of high-risk *in vitro* diagnostic medical devices (currently only four out of eight categories covered). These laboratories carry out several tasks for high-risk diagnostics, including e.g., infection control tests for blood transfusions. Part of the tasks of EURLs is funded by fees from notified bodies and Member States but a significant part may not be covered by fees. 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.

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

OBJECTIVES, SCOPE AND ACTIVITIES

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

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

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85 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).

86 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).

87 Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects (11597/24).

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

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – HS-g-25-22	Q3/2025	EUR 5 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to the EU reference laboratories in accordance with Article 198, paragraph 1, point (d), of Regulation (EU, Euratom) 2024/2509	HaDEA	Designated EU reference laboratories

HS-g-25-23 Direct grants to Member States' authorities for supporting the maintenance of the European Medical Device Nomenclature

POLICY CONTEXT

The implementation of Regulation (EU) 2017/745[88] and Regulation (EU) 2017/746[89] is a priority for the European Commission, as highlighted in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare, the Council Conclusions on the Future of the European Health Union of June 2024[90] and several debates in the EPSCO Council, the last one in December 2024.

To facilitate the functioning of the European database on medical devices ('EUDAMED'), the European Medical Device Nomenclature ('EMDN') is to be utilised by manufacturers for the registration of medical devices in the EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier.

88 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).

89 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).

90 Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects (11597/24).

The EMDN also plays a key role in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746, medical devices device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance, and post-market data analysis, etc. It will support all actors in their activities under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and provide key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.

To allow the Commission to fulfil its legal obligation in accordance with Article 26 of Regulation (EU) 2017/745, it is essential that the actor currently supporting the maintenance of EMDN, the Italian Health Ministry and the Region Friuli-Venezia Giulia, continue to provide their support and competences. The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified, since this activity can only be carried out with the support of the unique expertise of the Italian Ministry gained by developing medical device nomenclature at national level ('Classificazione Nazionale Dispositivi Medici').

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action will support the maintenance and update of the EMDN through:

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

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

a) an increase of knowledge and use of the nomenclature between Member States' authorities and stakeholders to respond to requests for information and clarifications linked to the nomenclature;
b) inclusivity of actors and capacity to adapt to innovation in the regular revision of codes and descriptors including granting of new codes and descriptors for devices not yet included in the nomenclature according to the state of the art as requested by the MDCG sub-group on nomenclature and provided through the public platform;
c) continued stability and maintenance of the EMDN encyclopaedia, the medical device dictionary; and

d) maintenance of the Union's global role in the medical device nomenclature and regulation by promoting the Union's system and encouraging its uptake by third countries.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – HS-g-25-23	Q3/2025	EUR 1 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities,

HS-g-25-24 Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients

POLICY CONTEXT

Medical devices and *in vitro* diagnostics have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of many diseases, including non-communicable diseases such as cancer, cardiovascular diseases or diabetes.

Medical devices are subject to Regulation (EU) 2017/745[91], while *in vitro* diagnostic medical devices are subject to Regulation (EU) 2017/746[92].

For the purpose of this action, orphan devices 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 and where no or only insufficient suitable alternative therapeutic or diagnostic options with expected similar clinical benefit and safety exist. Criteria for orphan devices are specified in guidance MDCG 2024-10 *Clinical evaluation of orphan medical devices*[93].

[91] 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).

[92] 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).

[93] MDCG 2024-10 Clinical evaluation of orphan medical devices.

The need to consider the specificities of orphan devices has been repeatedly highlighted as an area of priority by the Commission as well as by the Member States[94] and the European Parliament[95].

At the Union 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.

The level of clinical evidence that is required to place medical devices on the market has been increased by the MDR, including an increased need for pre-market clinical investigations for certain higher risk devices to verify their safety and clinical performance. These increased clinical evidence requirements present a challenge for devices specifically intended for use in rare diseases/conditions, or in specific indications for rare cohorts of patients with an otherwise non-rare disease/condition.

In many cases, orphan devices are intended for use solely or predominantly in minors and paediatric populations, and/or in emergency situations. Proactively generating clinical data within an appropriate time in small patient populations is particularly challenging, as is the case for vulnerable populations in light of the ethical and regulatory requirements to appropriately protect these populations, as well as greater practical challenges of performing clinical studies in certain cohorts such as infants and children.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to support innovation in the field of medical devices by supporting non-profit organisations or consortia that provide a platform for academic bodies, scientific societies, developers of devices, in particular SMEs, and NGOs with a specific interest in innovative medical devices to help foster and guide the development of orphan devices, in particular in areas of unmet medical needs and paediatric patients. It takes inspiration from the Paediatric Device Consortia Grants Program of the US Food and Drugs Administration ('FDA') and builds on the positive experience gained with action HS-g-23-65 call for proposals for a programme on orphan medical devices in particular targeting paediatric patients, launched under the 2023 EU4Health work programme[96].

A wide range of activities can be funded that support, among other things, the development, design, production and distribution or orphan devices, including intellectual property advising, prototyping, engineering, laboratory and animal testing, grant-writing, and clinical investigation design.

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94 Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects (11597/24).

95 Resolution on the urgent need to revise the Medical Device Regulation (2024/2849 (RSP)), October 2024.

96 2023 EU4Health Work Programme.

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

a) mapping unmet medical needs that could be addressed by orphan devices;
b) encouraging innovation and connecting relevant players (e.g., academia, scientific societies, users) with orphan device ideas with potential manufacturers;
c) mentoring and managing orphan device projects through the development process, including product identification, prototype design, device development, and marketing;
d) connecting developers of innovative devices and physicians to existing financing resources;
e) assessing the scientific and medical merit of proposed orphan device projects;
f) gathering and evaluating pre-clinical data to support the safety and/or performance of the orphan device;
g) providing assistance and advice as needed on business development, personnel training, prototype development, intellectual property protection and post-marketing needs;
h) advising about regulatory requirements to device developers in support of achieving CE marking for the orphan devices; and
i) supporting the demonstration of conformity with the relevant requirements laid down in Regulation (EU) 2017/745 or Regulation (EU) 2017/746 with a view to allowing the CE marking of the product building on the guidance MDCG 2024-10 including the scientific advice procedure from the expert panels on medical devices[97].

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

To accomplish this work, a successful entity should unite natural persons, associations 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 action is intended to promote the development of innovative orphan devices especially for paediatric patients, with a particular focus on devices responding to unmet medical needs.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – HS-g-25-24	Q3-Q4/2025	EUR 1 200 000
Procedure type	**Implemented by**	**Type of applicants targeted**

[97] See EMA pilot programme to support orphan medical devices New pilot programme to support orphan medical devices | European Medicines Agency (EMA).

Open call for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs, civil society organisations: associations, foundations, NGOs, enterprises (including social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit)

HS-g-25-25 Direct grant to Member States to provide regulatory or scientific advice to small and micro-enterprises to support the development and carrying out of the conformity assessment of devices, particularly innovative devices, and to facilitate the Union level coordination on medical device safety issues

POLICY CONTEXT

To ensure a high level of safety of medical devices and in vitro diagnostic medical devices, Regulation (EU) 2017/745[98] and notably Regulation (EU) 2017/746[99] introduced stricter regulatory requirements. The implementation of the new regulatory requirements remains a challenge for manufacturers and in particular small and micro-enterprises which have limited resources to adapt to the regulatory framework. Yet, small and micro-enterprises are well known to play a major role in the development of devices in the Union, in particular innovative ones. To keep the Union an environment conducive to innovation, it is critical to provide regulatory and scientific support to these players. National competent authorities are the best fitted actors to provide this advice as they have the expertise, network knowledge and linguistic capacity to interact with small and micro-enterprises.

At the same time, it is essential that safety issues related to medical devices arising from various sources, such as vigilance and market surveillance cases are assessed, and that coordination is ensured on those issues having a Union-wide impact. In this context, the already ongoing work by the Member States on mechanisms and capability of the assessment and handling of extraordinary medical device safety issues at Union level should be further strengthened in order for the system to not solely rely on multiple national assessments.

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 the Member States' authorities as they have the required competence and responsibility to implement the Union policies at national level.

The action also has a Union added value. It implements the EU4Health Programme's general objective to improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

Legal entities from Liechtenstein are eligible to participate in the project as associated partners without funding in accordance with Article 13(1)(iii), (2) and (3) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

Objectives of this joint action are to increase the scientific and clinical capability of the regulatory system- support innovation and clinical research of medical devices and in vitro diagnostic medical devices with a focus on small and micro-enterprises. In addition, the objective is also to further strengthen capabilities of the system in relation to safety issues of medical devices.

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98 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).

99 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).

This action may also entail the involvement of the expert panels established in Regulation (EU) 2017/745 and/or other relevant key players in the field of medical devices with regulatory and/or scientific expertise.

Activities:

The scope of the activities under this action encompasses the delivery of regulatory and scientific advice to manufacturers, including:

a) targeted regulatory advice on how to navigate Regulation (EU) 2017/745 and Regulation (EU) 2017/746 taking into account the devices' characteristics and support for the development of technical documentation;
b) preclinical scientific advice.

Moreover, the activities under this action aim at supporting Union level coordination for the assessment and handling of extraordinary medical device safety issues through:

a) identifying and defining interfaces between the existing Medical Device Coordination Group working groups in case of an extraordinary safety issue and the involvement of other relevant bodies (e.g., expert panels);
b) development of relevant procedures and protocols for communication and information sharing on extraordinary safety issues with Union wide impact between the Member States;
c) involvement of scientific expertise notably of the expert panels (set up under Regulation (EU) 2017/745) in the assessment of safety issues with Union wide impact,
d) exchange between the Member States of core data relating to medical device safety, clinical benefit, risk and mitigation actions.

EXPECTED RESULTS AND IMPACT

The expected results under this action include the delivery of regulatory and scientific advice by national competent authorities, such as:

a) micro- and small enterprises are supported and incentivised to proceed with the development of devices in the Union;
b) micro- and small enterprises are supported in preparing regulatory submission files meeting regulatory requirements;
c) conformity assessment activities by notified bodies are facilitated through enhanced technical file quality and less or no iterations thus shortening the overall process and the associated costs;
d) time to reach market is shortened, in particular for innovative medical devices; and
e) patients benefit in a timely manner from safe and performant devices, including innovative ones able to meet their needs.

Union level coordination for assessments and handling of extraordinary medical device safety issues:

a) increase the scientific and clinical capability of the regulatory system at Union level;
b) ensure that extraordinary safety issues can be addressed effectively at Union level;
c) increased responsiveness and cohesion of the Union system to high profile safety issues;
d) more cohesive communication and interaction with manufacturers on safety issues; and
e) increased safety of medical devices in the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grants – HS-g-25-25	Q3-Q4/2025	EUR 4 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	EU Member States' authorities and authorities of EEA countries associated to the EU4Health Programme (Norway and Iceland)

4.3. IMPLEMENTATION OF THE CLINICAL TRIALS REGULATION

HS-g-25-27 Direct grants to Member States' authorities to support implementation of the Clinical Trials Regulation and to improve the clinical trials landscape with Member States and EEA countries, including through pilots and training

POLICY CONTEXT

The main policy context of the project is the implementation of Regulation (EU) No 536/2014[100] and Commission Implementing Regulation (EU) 2017/556[101]. Also relevant are the activities pursued in the context of the Good Clinical Practice Inspector Working Group hosted by the EMA. The Clinical Trials Regulation is directly applicable in all EU/EEA countries and sets out one common set of rules for the submission and assessment of clinical trial applications for medicinal products of human use. The assessment, management and supervision of clinical trial remain Member States' responsibility.

Regulation (EU) No 536/2014 and Regulation (EU) 2017/556 became applicable in the EU/EEA in 2022 and, after a 3-year transitional period, they took full effect as of 31 January 2025. At the same time, there has been a rapid evolution of science and innovation in the clinical trial environment as well as increasing experience with the new regulatory environment.

Assessors of clinical trials applications, including national competent authorities and ethics committees, rely on robust scientific knowledge and up-to-date regulatory practices. The new coordinated assessment process of clinical trial applications requires new ways of collaboration as well as increased trust and reliance between Member States concerned. Cooperation on the scientific and ethical review is an important enabler toward harmonisation and streamlining of the clinical trials authorisation process. Therefore, development of regulatory expertise and alignment of assessment processes across the network, irrespective of the volume of clinical trials in the Member States, is equally important. This emphasis on capacity building ensures consistent and streamlined implementation, and efficiency gains of the regulatory framework throughout the network favouring multi country clinical trials, hence supporting the attractiveness of the Union for clinical research as pointed out in the Draghi Report on the future of European competitiveness. Harmonisation and increased efficiency are needed to enhance compliance with Good Clinical Practice (GCP)[102] that ensure patients' access to high quality, safe and effective medicines.

A fundamental condition for a successful implementation of the regulatory framework is a close collaboration and alignment among the EU/EEA countries. They are requested to assess increasingly complex clinical trial applications, for example, involving investigational medicinal products with medical devices (Advance Therapy Medicinal Products ('ATMPs')). In addition, specific training would be needed for the assessment of decentralised trials[103], and the use of digital tools and AI which uptake should be promoted in line with the Draghi report and the mission letter from Commission President von der Leyen to the Commissioner for

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

101 Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council (OJ L 80, 25.3.2017, p. 7).

102 Good clinical practice.

103 Decentralised trials are those clinical trials conducted outside the traditional 'clinical trials site'. It also covers clinical trials using decentralised elements i.e. digital tools for remote collection of data. See: Facilitating Decentralised Clinical Trials in the EU | European Medicines Agency (EMA).

Health and Animal Welfare. However, some responsible authorities need to continue to gather experience and build expertise to keep up with the scientific and technological developments.

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 EU Member States and EEA Member States associated to the EU4Health Programme (Norway and Iceland) authorities as they have the required competence and responsibility to implement the Union policies at national level.

This joint action also has a Union added value. It will, among other things, contribute to the policy priority to implement the Pharmaceutical Strategy for Europe. It implements the EU4Health Programme's general objective to improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c), (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The scope of the activities is to ensure the necessary expertise and competences as well as trust for reliance on existing assessments and cooperation as enabler of alignment in the network to effectively and efficiently assess clinical trial applications, and inspect clinical trials performed in line with the scientific and technological developments and increasing regulatory experience.

Building on the activities and deliverables of ACT EU priority action on training, the Joint Action SAFE CT[104], and of the Joint Action CT-CURE[105] on the regulatory assessment of clinical trials during public health emergencies, the activities are:

a) to develop common training materials and best practices for assessors, for the coordinated review or some aspects that are assessed at national level during clinical trials authorisation application, including the handling of innovative products (e.g., ATMPs, products developed in combination with devices) and technological advances (in coherence with the EU Network Training Centre (EU NTC)[106] where appropriate) through trainings of assessors by assessors, workshops, and face to face meetings reinforce capacity and promote trust amongst clinical trial assessor toward efficiency gains through reliance on existing assessments and to streamline the assessment of national aspects, where possible;
b) to define and promote common assessment criteria for complex clinical trial applications where the rules of the Clinical Trials Regulation are intertwined with other regulatory frameworks;
c) to develop and promote best practices to be used as a source of information on how to assess complex clinical trials;
d) to develop common training material for the GCP and bio equivalence inspectors to facilitate cooperation in inspecting national and multi-national clinical trials, including for new products (e.g., ATMPs, products developed in combination with devices) and AI-powered tools (e.g., updating of the current GCP curriculum) using the concepts of e-learning;

104 2021 EU4Health work programme, action HS-g-18.3.1 Safety assessment cooperation and facilitated conduct of clinical trials ('SAFE CT').

105 2021 EU4Health work programme, action CP-g-01.1.2 Clinical Trial Competitive multinational assessment timelines in the European Union ensuring Regulatory Excellence ('CT-CURE').

106 EU Network Training Centre.

e) to establish and implement a common EU/EEA-wide on-boarding process for new GCP inspectors and a framework for on-the-job training for GCP and bio equivalence inspectors (e.g., supporting observers to national and EMA coordinated inspections);
f) to promote communication between clinical assessors and GCP inspectors, e.g., by establishing communication channels, creating an overview of triggers for inspections, datasets for exchange of information etc.;
g) to facilitate exchange programmes among partners of the Union clinical trials network through, observership, short secondments and on the-job-coaching and training.

The objectives for assessors are:

a) to train assessors active in the assessment report (both for coordinated review and the Member States specific review) for coordinated assessments and cooperation in the assessment of national aspects. Foster knowledge-sharing and cooperation to build trust for increased reliance among clinical trials assessors and medical research ethics committees within and across EU/EEA countries;
b) to streamline the assessment of complex clinical trial applications by the responsible authorities so to ensure a harmonised implementation of the Clinical Trials Regulation;
c) to positively influence the harmonisation of the National Competent Authorities of EU/EEA countries, and the Union inspectors' network as a whole, while guaranteeing safe and robust clinical trials within the Union;
d) to facilitate a more uniform review process of clinical trials in the Union.

The objectives for GCP inspectors are:

a) to provide GCP inspectors with the knowledge and tools to inspect clinical trials sites and sponsor sites, including complex clinical trials with ATMPs or products developed in combination with devices and that may include AI-based results;
b) to foster joint efforts in harmonising inspection and trainings including capacity and capability improvement;

EXPECTED RESULTS AND IMPACT

The expected results for clinical trials assessors are:

a) strengthening of the Union regulatory network and ensure compliance with the Union regulatory standards and the Union GCP requirements;
b) reinforcing the implementation of Regulation (EU) No 536/2014 through the improvement, efficiency gains and streamlining of procedures;
c) strengthening of the role of the reporting Member State;
d) facilitating onboarding of new clinical trials assessors building on the knowledge gained by training and exchange programmes;
e) common assessment approach of complex clinical trials applications;

The expected results for the GCP inspectors are:

a) to reinforce implementation of the Implementing Regulation (EU) 2017/556 on GCP inspections procedures through the improvement and streamlining of procedures;
b) to facilitate onboarding of new GCP inspectors thanks to the knowledge gained by training and exchange programmes;
c) common approach applied by GCP inspectors for clinical trials including ATMPs, combined studies, AI-based procedures.

The overall expected impact is increased harmonisation, collaboration, and efficiency of GCP inspections and of the assessment of clinical trial applications with ATMPs, combined developed products, and AI-based results.

In addition, this joint action will contribute to building capacity to facilitate multi-country trials in the Union, including non-commercial ones, and facilitate the starting phase on new clinical trials, and the development of model templates.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – HS-g-25-27	Q4/2025	EUR 4 700 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	EU Member States' authorities and authorities of EEA countries associated to the EU4Health Programme (Norway and Iceland)

HS-g-25-28 Direct grants to Member States' authorities to support non-commercial sponsors active in clinical trials

POLICY CONTEXT

Since 31 January 2025, sponsors have to comply with Regulation (EU) 536/2014[107]..

Experience shows that a large proportion of clinical trials are conducted by non-commercial sponsors. For instance, over the period between January and March 2025, 272 clinical trial applications for multi-national trials were submitted. Of these, 30 was from non-commercial sponsors and 242 from commercial sponsors. Most of non-commercial sponsors submit their applications to one Member State only (398 applications for mono national trials). Moreover, key performance indicators of the ACT EU monthly reports on clinical trial submission suggest that non-commercial sponsors are more prone than commercial sponsors to withdraw applications or let the application lapse[108].

The support to non-commercial sponsor was identified as a key priority by ACT EU initiative (Accelerate Clinical Trials in Europe) involving the Commission, Heads of Medicines Agencies (HMA), and the European Medicines Agency (EMA)[109]. The activities listed in this project

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

[108] ACT EU Kye performance indicators reports - Documents - European Union.

[109] ACT EU one of the main activities on Support for non-commercial sponsors – European Union.

reflect the needs for additional Union funding to support non-commercial sponsors, complementing national mechanisms. One of the key problematic areas was to develop a European network of national helpdesks. This network of helpdesks will support non-commercial sponsors to conduct multi-national clinical trials in the Union[110].

Therefore, based on the figures that can be retrieved, and on the experience of national competent authorities, non-commercial sponsors need support to navigate through the regulatory requirements and the new working methods brought by Regulation (EU) 536/2014. A training specifically tailored to non-commercial sponsors was hosted by the European Medicines Agency and it had 1859 unique viewers. These numbers, amongst others, demonstrate that non-commercial sponsors require special attention, trainings and regulatory support both from their respective national competent authorities and from the Union regulators.

The results of a survey with non-commercial sponsors indicate the need to improve regulatory knowledge and raise awareness on available trainings and IT systems.

Non-commercial sponsors frequently rely on funding which comes partly or entirely from public funds or charities, or they must request regulatory and financial support to commercial entities. To maximise the valuable contribution of non-commercial sponsors and to further stimulate their research, measures should be taken by the Member States to encourage clinical trials conducted by those sponsors and the Union can help them with this endeavour. Financial support can contribute to achieving the objectives set out in Regulation (EU) No 536/2014.

Strengthening the ability of non-commercial sponsors to conduct clinical trials in the Union is crucial as these trials are investigating treatments for which there is no commercial interest, or they are looking at the effectiveness of treatments. Non-commercial sponsors trials are also instrumental for the investigation of treatment optimisation of oncology medicines among others.

As the experience from the COVID-19 pandemic shows, a large majority of clinical trials applications to search for treatments or possible new indications for existing ones were conducted by non-commercial sponsors with multinational trials conducted across Europe playing a key role to bridge the medical and research field[111].

This joint action also has a Union added value. It will, among other things, contribute to the policy priority to implement the Pharmaceutical Strategy for Europe. It will implement the EU4Health Programme's general objective to improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c), (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This joint action will support those researchers that are willing to conduct clinical trials for non-for-profit purposes and ultimately create a conducive environment for research and development in Europe.

Objectives of this joint action are to:

110 ACT EU activity on the support for non-commercial sponsors regarding funding opportunities: Exploratory analysis on funding to support academic sponsors conduct multi-national clinical trials.

111 European Medicines Agency / Emergency Task Force and European Commission workshop on lessons learned on clinical trials in public health emergencies | European Medicines Agency (EMA).

- support non-commercial sponsors to submit high quality clinical trial applications;
- generate robust and reliable data through larger clinical trials, especially for rare and ultra-rare diseases;
- reduce inherent administrative burden and provide regulatory clarity;
- help delivering some activities that have been already started under the ACT EU[112] initiative but miss the financial instrument.

Activities of this joint action are to:

a) develop training materials to inform of the European regulatory requirements (training for future regulatory trainers), including translations as necessary;
b) facilitate establishment of a European network of national helpdesks to support cooperation mechanism between Member States;
c) develop Union templates which will help sponsors to launch in a timely manner a clinical trial in multiple Member States.

EXPECTED RESULTS AND IMPACT

Expected results of this joint action are:

1. registering an upward trend of clinical trial applications submitted by non-commercial sponsors in multiple countries;
2. witnessing an increased number of Member States involved by non-commercial sponsors;
3. lowering the number of clinical trial applications that must be withdrawn because of the regulatory complexity or because the low quality of the documents; and
4. lowering the number of clinical trials lapsed because non-commercial sponsors are not able to provide the necessary documents within the timeline set by Regulation (EU) No 536/2014.

By improving regulatory understanding and providing support where needed, non-commercial sponsors should be able to:

a) increase the population size of the trial participants and consequently issuing more robust and reliable data; and
b) investigate those clinical research areas often neglected by commercial sponsors because not commercially viable.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – HS-g-25-28	Q4/2025	EUR 1 800 000
Procedure type	**Implemented by**	**Type of applicants targeted**

112 Accelerating Clinical Trials in the EU. This programme is an initiative launched in January 2022 by the Commission together with European Medicines Agency (EMA) and Member States. As part of this programme, one of the 11 priority actions (priority action 2) is to support non-commercial sponsors. This leverages existing national activities that are going to be mapped in the course of 2025.

Direct grants to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	EU Member States' authorities and EEA Member States' authorities associated to the EU4Health Programme (Norway and Iceland)

4.4. GLOBAL HEALTH

HS-g-25-29 Direct grants to Member States' authorities to maximise the impact of the EU Global Health Strategy

POLICY CONTEXT

Following the publication of the EU Global Health Strategy in November 2022, better coordination to strengthen the Union's leadership in global health is essential to maximise the collective impact of Union contributions to global health and to shape a new global health order based on the Union fundamental values.

Initial steps were taken with the 2023 EU4Health work programme, supporting the European Joint Action to maximise the impact of the EU Global Health Strategy[113] ('JA GHI'). Building on the results and lessons learned emanating from the JA GHI and the outcomes of the suggestions forum, a second phase under a new direct grant for a 2-year period is desirable.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because the Team Europe approach is key to the strategy's implementation and Member States' authorities have the required competence and responsibility to implement the Union policies at national level. The action will further take into account the health in all policies approach of the EU Global Health Strategy and ensure coordination between different sectors as appropriate.

This joint action also has a Union added value. It will contribute to the policy priority to implement the EU Global Health Strategy. It implements the EU4Health Programme's general objective to strengthen health systems (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this joint action is to continue to contribute to the implementation of the EU Global Health Strategy, strengthening the Union's leadership by continuing putting in place rolling mechanisms for closer coordination and synergies between the Member States and the Union institutions. To ensure the implementation of the EU Global Health Strategy, which outlines actions until 2030, it is recommended to follow up the JA GHI.

To that end, and subject to further political guidance, this joint action should:

a) build upon the outcomes and lessons learned of the JA GHI and integrate the recommendations from the suggestion forum as appropriate;
b) identify, coordinate and monitor current actions related to Global Health priorities while avoiding overlaps and ensuring optimal synergies with national strategies, actions and policies;
c) identify gaps and opportunities for collaboration across the Union and its Member States;
d) enhance external outreach to effectively showcase the Union's commitment to global health;
e) facilitate information and intelligence sharing between the Union and the Member States in relevant global health fora;

113 2023 EU4Health work programme, action HS-g-23-71-01 European Joint Action to maximise the impact of the EU global health strategy ('JA GHI').

f) promote improved coordination among stakeholders.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- The establishment of specialised platforms to facilitate the sharing of information, and coordination of actors in key focal points (Brussels, Member State capitals, Geneva and New York);
- Strengthening of the role of all Member States in global health and ensure solid governance arrangements with the Member States;
- Improvement of coordination between sectors particularly within Member States, and between Member States and EU institutions
- Production of periodic surveys on specific topics, and consolidated positions;
- Creation of a system to map political and financial efforts;
- Strengthening of the capacity in each Member State and expertise in global health;
- Improvement of information exchange and outreach within and beyond the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grants – HS-g-25-29	Q3/2025	EUR 2 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (joint action) in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

5. DIGITAL (DI)

DI-g-25-30 Direct grants to Member States' authorities for enhancing Health Data Access Bodies with particular focus on the secondary use of health data

POLICY CONTEXT

Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847[114] ('EHDS') includes the creation of a digital infrastructure (HealthData@EU) to facilitate the re-use of electronic health data for secondary uses, in which competent bodies (health data access bodies) manage the access to data and provide ICT infrastructure and crosscutting services such as terminology and interoperability.

The action DI-g-22-22.01 of the 2022 EU4Health work programme included a first set of direct grants for Member States to set up or prepare their existing health data access bodies in the context of the EHDS.

This action further supports Member States' authorities and authorities of EEA countries associated to the EU4Health Programme to establish or enhance health data access bodies and related services and infrastructures to achieve a HealthData@EU infrastructure in which health data access bodies have fully deployed the data business capabilities required by the EHDS regulation. The action also supports non-EEA countries associated with the EU4Health Programme in carrying out preparatory activities (e.g., analysis, design, and development activities) for the cross-border gateway for HealthData@EU.

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

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

This action supports the Europe's Beating Cancer Plan by making health data more easily available cross-border for research and other purposes, including for cancer research. It builds on the synergies between the cancer and digital strands of EU4Health by providing health sector wide infrastructures to support the Europe's Beating Cancer Plan in the area of research and innovation. This action should build on the work of past and on-going funded projects related to the implementation of EHDS such as EHDS2 Pilot, TEHDAS, and TEHDAS2. This action also complements actions launched under the Digital Europe Programme and Horizon Europe on the EHDS, digital health and health data. For example, it will have a direct link with the SHAIPED project which aims to leverage EHDS and Health Data Access Bodies, and possibly Testing and Experimentation Facilities ('TEFs') and European Digital Innovation Hubs ('EDIHs') to enhance the pathways that make use of health data access bodies and testing and experimental facilities to develop AI solutions. Moreover, it complements domain specific projects launched under the Digital Europe Programme, for example, for cancer images, genomics, and intensive care unit data.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to support the establishment and expansion of capabilities in health data access bodies ('HDABs'). This will enable their seamless integration in the EHDS

[114] OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

and with HealthData@EU. It will enhance the efficiency of the reuse of health data across Member States, facilitating research and innovation of new medical technologies, such as for cancer or communicable diseases, including for example development of innovative artificial intelligence solutions, as well as streamlining the reuse of health data for policy-making and regulatory activities.

The scope of this action encompasses the deployment of essential digital business capabilities that stem from the obligations enshrined in Chapter IV of the Regulation on the European Health Data Space for setting up national HDABs in Member States' authorities and authorities of EEA countries, which include:

a) data access application management system - to streamline the process of requesting and granting data access;
b) national dataset catalogue of health data - to provide a comprehensive and searchable listing of available health data sets;
c) secure processing environment - to ensure that health data is processed in a secure and compliant manner;
d) cross-border gateway for HealthData@EU - to facilitate the safe and efficient exchange of health data across borders;
e) health data quality enhancement - to improve the accuracy, completeness, and reliability of health data;
f) opt-out management system - mechanism to allow natural persons to opt-out from secondary use;
g) HDAB transparency portal – to make publicly available information related to secondary use of health data (e.g. applications, permits, results).

The activities within this action include the initial design of the digital business capability in scope, where high-level frameworks and blueprints for the digital business capabilities are planned; followed by the development phase, where these plans are transformed into functional, operational systems; and concluding with the deployment stage, where the newly developed capabilities are integrated and launched into real world services. Throughout this process, it is fundamental to focus on adherence to applicable regulatory requirements, alongside ensuring the interoperability, scalability, and long-term sustainability of the implemented solutions.

The scope of this action takes into account the objectives in the following order of priority:

1. Primary aim: Support EU/EEA countries associated with EU4Health programme that have not previously received EU4Health grants for the development of activities, to enable them to initiate or further develop activities a) to e).
2. Secondary aim: Support EU/EEA countries associated with EU4Health programme that have received previous EU4Health grants for all or some of the activities a) to e), to develop new activities/business capabilities not covered by the previous call of WP2022.
3. Tertiary aim: Support non-EEA countries associated to the EU4Health Programme to conduct preparatory work (e.g., analysis, design, and development activities) for the cross-border gateway for HealthData@EU.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

a) enhanced readiness to meet the requirements prescribed by the EHDS Regulation applicable to health data access bodies;
b) established connectivity between health data access bodies and the HealthData@EU infrastructure, enabling multi-country discovery and access to health data for secondary uses.

The expected impact of this action is a more efficient secondary use of health data for purposes such as research and innovation (for example in cancer), personalised medicine, policy-making, official statistics, patient safety and regulatory activities, while ensuring a common approach, as set out in the proposed EHDS regulation. The rollout of these Health Data Access Bodies and HealthData@EU will result in a more efficient process for reusing health data, for example in the research and innovation activities related to the development of artificial intelligence.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Direct grants – DI-g-25-30	Q3/2025	EUR 14 400 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States in accordance with Article 198, paragraph 1, point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

DI-g-25-31 Call for proposals for health data for biotech innovation leveraging the European Health Data Space

POLICY CONTEXT

The intersection of health data and artificial intelligence ('AI') is poised to accelerate breakthroughs in the biotechnology ('biotech') industry, with the potential to transform human health, drive economic growth, and foster innovation. The EU, with its unparalleled talent pool, innovative industries, and robust regulatory frameworks, is strategically positioned to capitalize on this opportunity to also achieve the ambition of an AI continent. However, the biotech sector faces significant challenges, including the need for high-quality data, secure data access frameworks, streamlined regulatory processes, overcoming deploying challenges and enabled to scale up.

Regulation (EU) 2025/327 on the European Health Data Space ('EHDS') is a key initiative that aims to address some of these challenges by providing a secure and efficient framework for health data access and reuse across the Union. Furthermore, European data sharing and research infrastructures play a crucial role in facilitating access to high-quality health data, particularly in the fields of genomic, cancer, and brain research. The federation of these infrastructures is essential for supporting innovation, driving discovery, and knowledge promotion.

Building on this foundation, to unlock the full potential of the biotech sector, it is essential to support a coordinated approach on how to leverage health data and research infrastructures (and in particular genomics, cancer datasets, metabolomics studies, proteomics databases, and clinical trial networks) in the context of the EHDS frameworks to accelerate and promote innovation. This will enable the unlocking of new opportunities for innovation, drive growth, and improve health outcomes across the Union To fully harness the potential of the biotech sector, collaboration with the EU's AI Factories will be pivotal. These AI factories can act as incubators for innovation, enabling the integration of health data insights with AI capabilities to create next-generation biotech solutions.

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 (a) and (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The general objective of this action is to **accelerate the development and deployment of AI and digital solutions in the biotech sector driven by health data**, ensuring its secure and responsible use through the EHDS and leveraging AI Factories to augment these efforts.

Objectives:

- **Create a multistakeholder platform** that brings together the biotech industry, data holders, healthcare providers, patient organisations, regulatory bodies and AI Factories to exchange best practices on data access, AI applications, and innovation acceleration, facilitating collaboration, knowledge-sharing, and innovation in the biotechnology sector.
- **Identify and prioritise the most promising digital / AI applications for the biotechnology sector**, based on criteria such as potential impact on health outcomes, feasibility, technological maturity, and alignment with sectoral needs. Potentially, while also leveraging AI Factory resources for enhancement and validation, rapid prototyping and testing of AI-driven biotech solutions, enhancing the speed and efficiency of bringing innovations from concept to healthcare implementation.
- **Analyse the challenges and barriers to the development and deployment of digital / AI solutions in the biotechnology sector**, including data quality and availability, regulatory frameworks, ethical and privacy concerns, intellectual property ownership, technical barriers, and scientific validation, and identify potential solutions or strategies to address these challenges, guiding the effective utilization of the EHDS.
  Develop concrete recommendations to support the coordinated development of the EHDS for digital / AI solutions in the biotechnology sector, including for policymakers, industry leaders, and researchers, with a focus on fostering innovation, improving health outcomes, and enhancing the competitiveness of the Union's biotechnology sector.

  This action aims to bring together biotech sector industry, developers of AI solutions, Member States' authorities active in the area of secondary use of health data and Research infrastructures.

Activities:

1. **Establish a multistakeholder platform/community of practice**: create a platform that brings together biotech industry, research institutions, healthcare providers, patient organisations, and regulatory bodies and AI Factories to facilitate collaboration,

knowledge-sharing among stakeholders, and the discussion of challenges in the use of AI in the biotechnology sector.

2. **Conduct a landscape analysis**: map the current state of leveraging health data for AI in the biotech sector and identify the most relevant health datasets for the biotech sector, based on criteria such as potential impact on health outcomes, feasibility, and alignment with sectoral needs. Building on existing projects. Potentially incorporate also the AI Factories in this landscape analysis to also explore further application potential.
3. **Develop a strategic roadmap**: create a roadmap for the development, deployment, and scale-up of effective AI solutions in the biotech sector, including recommendations for policy-makers, industry leaders, and researchers. Promote the adoption of standardized data formats and frameworks that facilitate the role data and research infrastructure relevant to the biotech sector, taking into account AI Factory capabilities and building on existing projects and activities in this area.
4. **Pilot the roles for health data infrastructures under the EHDS frameworks**: This activity involves analysing and piloting the roles, and the potential federation of, specific health data infrastructures (genomic, cancer imaging, and brain) within the EHDS frameworks, as well as access to computing resources, and other related data and support services, to support AI-driven biotech innovations. The analysis shall examine the current state of these infrastructures, identify gaps and limitations, and pilot their integration with the EHDS frameworks to enable seamless data sharing and access. The goal is to demonstrate the value of these infrastructures in supporting AI applications in the biotech sector and provide recommendations for integration of such infrastructures into the EHDS frameworks.
5. **Develop case studies**: create case studies of successful AI applications in the biotech sector, and share them with stakeholders to promote best practices, pathways and knowledge-sharing, these case studies should focus on explainable AI.
6. **Integrate AI Factory Expertise:** Incorporate AI Factory technological advancements in collaboration with the use of the EHDS infrastructure, for simulations and analytics to refine and optimise biotech AI solutions, ensuring alignment with healthcare needs.
7. **Monitor and evaluate progress**: pilot a methodology and tools to monitor and evaluate progress towards the strategic roadmap objectives, to provide insights and adjustments needed for continuous improvement.

The action should leverage existing initiatives like the 1+ Million Genomes and data infrastructures proving access to health data relevant for the biotech industry.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- **Increased collaboration and knowledge-sharing:** establish an active network of stakeholders, encouraging collaboration and knowledge-sharing among biotech and healthcare sectors.
- **Accelerate innovation in the Union's biotech industry:** support the development and deployment of effective digital / AI solutions in the biotech sector, driving innovation and competitiveness of the Union's biotech industry, including through AI Factory-enabled advancements.
- **Enhanced health outcomes:** facilitate the broader adoption of digital / AI solutions in the biotechnology sector enhancing patient care, diagnosis accuracy and treatment efficiency across the Union.

- **Regulatory clarity:** clarify regulatory requirements and standards/specifications for AI development and deployment relevant to the biotech sector and provide pathways for biotech stakeholders and for health data and research infrastructures integration into the EHDS frameworks.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for Proposals – DI-g-25-31	Q3-Q4/2025	EUR 14 386 810
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Type of targeted entities partners representing at least the following stakeholders: • biotech sector industry, • developers of AI solutions, • Member States' authorities active in the area of secondary use of health data from at least 3 Member States, • Research and health data infrastructures with experience in development and validation of AI solutions.

6. OTHER ACTIVITIES (OA)

OA-g-25-33 Call for proposals to contribute to the organisation of conferences

BACKGROUND

The work programme will support the organisation of Union-wide conferences which will meet the objectives of Regulation (EU) 2021/522.

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

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

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

OBJECTIVES, SCOPE AND ACTIVITIES

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

The Commission considers that proposals requesting an EU contribution of EUR 200 000 would allow this specific challenge to be addressed appropriately.

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

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

EXPECTED RESULTS AND IMPACT

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

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

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

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

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

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Indicative call publication**	**Indicative Budget**
Call for proposals – OA-g-25-33	Q3-Q4/2025	EUR 600 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grants)	HaDEA	Public or non-profit entities with expertise in organising events in the public health domain

B. PROCUREMENT

The overall allocation reserved for procurement contracts in 2025 amounts to EUR 281 702 582.

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

In 2025, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts) or administrative arrangements (including service level agreements, co-delegations, and memoranda of understanding) with other Commission services (e.g., JRC, DIGIT, COMM) or Union bodies and agencies (e.g., European Environmental Agency) to support priorities in the thematic areas listed below. The type of agreement will be identified according to the characteristics of the service.

1. CRISIS PREPAREDNESS (CP)

CP-p-25-34 Ever-warm facilities (EU FAB) for vaccines production – the Commission's Health Emergency Preparedness and Response Authority (HERA)

Although the Union has substantially scaled up the manufacturing capacities for COVID-19 vaccines, it remains crucial that sufficient, agile manufacturing capacities will be maintained for possible future health threats, even when there is no more demand on the market.

EU FAB will continue to make available a network of 'ever-warm' production capacities for selected vaccine platforms in the Union, including qualified staff, manufacturing lines, clear operational processes, quality controls and regular investments in infrastructure, thus allowing the Union to be better prepared and respond to future health threats. This action will continue to support the large-scale production of vaccines in the EU/EEA, to maintain and quickly guarantee access to sufficient production capacity in cases of public health emergency. The facilities must be operational during non-crisis times, during which they can be used for their regular activities. In case of activation, they must be capable to produce and supply the quantities of vaccines to be agreed, upon request and within the requested timeframe.

The objective is to ensure that sufficient and agile manufacturing capacities for different vaccine types and technologies (e.g. mRNA-based vaccines, protein-based vaccines and vector-based vaccines) during the period between public health emergencies, also referred to as *"peacetime"*, to ensure that in the initial phase of a public health emergency sufficient manufacturing capacities are available before industry has scaled up their own production.

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

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and support innovation regarding such products to enhance preparedness for future health emergencies in synergy with Horizon Europe. It implements the EU4Health Programme's general objective of improving the availability, accessibility, and affordability of crisis-relevant products with a focus on pathogens with pandemic potential (Article 3, point (c),

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

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(b).

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

Indicative budget for this thematic area: EUR 111 464 590

Implementation by: HaDEA

CP-p-25-35 Manufacturing investments and manufacturing capacity reservation contracts to strengthen supply of medical countermeasures (HERA)

This action will aim at mitigating structural risks, reinforce supply chains, encourage diversification and boost manufacturing of medical countermeasures. The action will boost Europe's capacity to produce and innovate in the manufacturing of medical countermeasures relevant for preparedness purposes and crisis response and will aim to address vulnerabilities in the supply chains of medical countermeasures. This action is expected to align with the upcoming Medical Countermeasures Strategy and EU Preparedness Union Strategy, when available.

Potential services could include:

- Studies to assess and define the production and supply chain network for specific products at an EU level to inform MCMs policies and industrial interventions for decision-making.
- Studies to plan and analyse the impact of more resilient and robust industrial interventions.
- Piloting of industrial interventions to start production, scale-up production, and/or other measures that increase supply of MCMs and/or their components or ingredients/APIs in the EU.
- And/or piloting reservations of manufacturing capacity, increasing inventory levels for selected medical countermeasures, such as raw materials, APIs, medicines, medical devices and/or in vitro medical devices, and/or personal protective equipment.

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

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(b).

Indicative type of contracts/supply: use of existing framework contracts, open procedure / negotiated / competitive for the launch of a new framework contract, and/or other procurement procedures.

Indicative budget for this thematic area: EUR 40 000 000

Implementation by: HaDEA/HERA

CP-p-25-36 Support to speed up the development of, access to and/or uptake of medical countermeasures (HERA)

Accelerate the development, access, and uptake of innovative and/or repurposed medical countermeasures ('MCM'), is crucial to ensure that the Union can adequately prevent, prepare for and respond to serious cross-border threats to health. This action has two main objectives:

1. **Supporting the development of, access to and/or uptake of medicinal MCM** This action is intended to support the development of, access to and/or uptake of medicinal MCMs (e.g. vaccines and therapeutics) including the ones in advanced clinical phases, in particular following the opinions issued by the Clinical Trial Coordination Mechanism ('CT-CM') group[115].
2. **Supporting the development of, access to and/or uptake of non-medicinal MCM** This action is intended to allow HERA to support the development of, access to and/or uptake of non-medicinal MCM, including medical devices, in vitro diagnostic devices, personal protective equipment and/or other innovative health technologies, necessary to improve preparedness and response to serious cross-border health threats.

This action can include the following activities:

a) supporting advanced clinical studies and/or trials, performance evaluation or similar studies for MCMs needed to prepare for and respond to health emergencies;
b) supporting development, manufacturing and/or putting on the market innovative and/or repurposed MCM for 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);
c) supporting public procurers with the uptake of innovative and/or repurposed effective MCMs, enabling them to use their purchasing power to incentivise development of next-generation products which are not yet available on large scale commercial basis;
d) supporting accessibility and availability activities, such as pull incentive schemes (e.g. revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards or milestone payments) for AMR MCMs and/or other MCMs with existing market failure.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures, to support innovation and access regarding such products and to ultimately enhance preparedness for future health emergencies in synergy with Horizon Europe. It

[115] The CT-CM group, a sub-group of the HERA Board, was newly established in 2024 to provide strategic guidance on clinical trials and their funding in the context of public health emergencies. The set-up of this group follows the call from Member States and scientists to address non-regulatory barriers in the clinical trial eco-system identified during the COVID-19 pandemic, such as the fragmentation in clinical data generation and the lack of coordination in the funding of clinical trials.

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

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(a).

Indicative type of contracts/supply: use of existing framework contracts, open / negotiated / competitive procedure for the launch of a new direct/framework contract, and/or other procurement procedures.

Indicative budget for this thematic area: EUR 52 732 652

Implementation by: HaDEA/HERA

CP-p-25-37 Purchase, innovation and deployment of medical countermeasures in emergency situations (HERA)

The action aims to procure and supply essential crisis-relevant products for which security of supply needs to be assured in the Union complementing Member States' reservation and stockpiling actions, as well strategic stockpiles developed at Union level. In particular, it will reserve capacities for the production and/or purchase of medical countermeasures ('MCMs') (as well as medical countermeasures deployment) in case of a health emergency or potential development of a serious cross-border health threat or recognised public health emergency, including caused by any of the priority threats identified by HERA in its threat assessment, using a Member State driven approach. This action should also allow the supporting of intelligence gathering, research and innovation in case of outbreaks and other cross-border health crisis, e.g. through clinical trials linked to specific countermeasures needed to address the health threat or by performing specific tests including sequencing in samples to detect a given threat.

The action will support and complement Member States' preparedness and response capacities as well as capacities of selected international partners. The activities will primarily focus on products with a Union marketing authorisation or CE marked but could under specific circumstances to be agreed upon with Member States, also include products under development or not yet authorised/certified/placed on the market in the Union. The action aims at purchasing medical countermeasures or reserve manufacturing capacity and assigning these capacities for orders placed by the Union's contracting authorities and/or the Commission, and/or to supporting intelligence gathering in relation to MCMs and/or research and innovation during emergencies, in synergy with emergency research activities funded under the Horizon Europe programme. This action will also support the provision of adequate logistics and transports services ensuring that medical countermeasures are safely and timely delivered to Member States in case of need and in full compliance with national and international regulations. Logistics and transport services can also support the development and manufacturing of medical countermeasures through the transportation of raw materials, investigational medicinal products and samples for research and development or clinical trials.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures, including critical medicines in shortage, against public health threats, support their innovation and thus improve preparedness for future public 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: use of existing framework contracts, open procedure / negotiated / competitive for a new framework contract, or other procurement procedures or contracts for the purchase or reservation of production and supply of relevant medical countermeasures, including their deployment; and/or for intelligence gathering of medical countermeasures.

Indicative budget for this thematic area: currently no budget allocated. The exact budget for this action will depend on the needs and the specific countermeasure to be procured with a ceiling of EUR 70 000 000 within HERA's budget share for 2025[116]. In the recent past, a similar action was performed with a budget of about EUR 46 000 000[117]. Budget will be mobilised in case of a cross-border public health emergency or potential development of a serious cross-border public health threat or recognised public cross-border health emergency, including caused by any of the priority threats identified by HERA in its threat assessment.

Measures under this action are not targeted at shortages of medicinal products in the regular supply chain and do not anticipate implementation of provisions in the proposed pharmaceutical package and the proposed Critical Medicines Act.

Implementation by: HaDEA/HERA

CP-p-25-38 IT development for early warning, modelling, simulation and forecasting – ATHINA 2.0 (HERA)

Under the 2022 EU4Health work programme, HERA launched action CP-p-22-01.03 to design, develop, deliver and maintain HERA's Advance Technology for Health Intelligence and Action IT System ('ATHINA'). This first action developed the basic features, first modules (Surveying and Public Health/Medical Countermeasures Case Management) and the necessary transversal backbone for the operationalization of ATHINA. During the implementation of this action there was also further functional and non-functional analysis and data modelling for future modules to be developed, namely the information systems linking module, the threat assessment module, the simulation and analytics modules and the emergency response module.

This action builds on action CP-p-22-01.03 of the 2022 EU4Health work programme and aims at expanding ATHINA minimum viable product on the basis of ongoing assessment of needs and including Artificial Intelligence ('AI'). As such, this action will support the full development of the information systems linking module, the threat assessment module, the simulation and analytics modules and the emergency response module. The development of the additional modules identified in the first version of ATHINA, will lead to a fully developed and robust tool that will provide a better preparation and response in case of cross-border health threats.

This action supports the policy priority to be better prepared to respond to serious cross-border health threats. It contributes to the achievement of the EU4Health Programme's general

116 Total HERA 2025 budget: EUR 357 645 165 (see page 8).

117 For more details see: HADEA/2022/NP/0014-Supply of Modified vaccinia ankara against monkeypox.

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: use of existing framework contracts and/or other procurement procedures, and/or co-delegation to DG DIGIT.

Indicative budget for this thematic area: EUR 12 000 000

Implementation by: HaDEA/HERA

CP-p-25-39 Global and EU wastewater sentinel system (HERA)

Wastewater surveillance plays a crucial role in protecting public health by providing early detection of disease outbreaks, monitoring community health trends, evaluating public health interventions, and supporting environmental health initiatives.

The current European wastewater-based infrastructure is still in early stages of development, and it is therefore critical to continue the institutionalisation of an effective wastewater surveillance system, to ensure that relevant data are promptly provided to competent health authorities at European level. There is a need to accommodate an increased sampling of the current supersites and to be able to enlarge the number of supersites mainly in the EU, but also beyond.

This action builds on action CP-p-24-18 from the 2024 EU4Health work programme and aims to continue supporting the ongoing activities to a global dimension and contributes to the horizontal policy priority aimed at fighting climate change.

This action should continue to cover testing of wastewater samples on the request of the Commission in strategic sites through e.g., PCR analysis of SARS-CoV-2, PCR analysis of several pathogens, next-generation-sequencing measurement and shotgun metagenomics in untreated wastewater sample, measurement of pollutants of concern in untreated wastewater samples. The services will also include the supply of sampling and packaging materials and equipment for wastewater samples collection and analysis from the super-sites to the analytical facilities.

This action will continue to contribute to:

a) building on and cooperating with the joint action on wastewater surveillance EU-WISH[118] and the global consortium for wastewater and environmental surveillance for public health ('GLOWACON')[119];
b) operationalising the EU's sentinel system;
c) supporting cooperation with international stakeholders in a global effort, in line with GLOWACON; and
d) supporting the coordination at global level to organise simultaneous testing under pre-defined conditions.

This action supports the policy priority to be better prepared to respond to serious cross-border health threats. It contributes to the achievement of the EU4Health Programme's general

118 Home | EU-WISH.
119 EU4S (europa.eu).

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: use of existing framework contract(s)

Indicative budget for this thematic area: EUR 8 000 000

Implementation by: HaDEA

CP-p-25-40 Support to the Commission on gathering intelligence on priority threats and medical countermeasures (HERA)

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

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

This action builds on action CP-p-23-14 from the 2023 EU4Health work programme. Synergies with the ECDC will be considered when threat identification and analysis activities are envisioned.

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 (a), (b) and (c), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

CP-P-25-41 HERA's training and exercise programme for management of medical countermeasures (HERA)

Strengthening knowledge and skills in preparedness and response related to medical countermeasures is essential to improve European preparedness and response capacity to cross-border health threats and is one of HERA's main tasks. In close cooperation with Member States, HERA is implementing a targeted training and exercise programme that will ensure the necessary capacity building to prepare and respond to health threats and to ensure supply-chain

security for medical countermeasures in the continent, contributing to European and global health security.

HERA's training and exercise programme is comprehensive, covering all aspects linked with the development, production and distribution of medical countermeasures, supporting the development of preparedness, readiness and actual response capacities of Member States to respond to a cross-border health crisis, regardless of its nature. The training and exercise programme also aims at strengthening coordination and solidarity at Union level, and at fostering and developing common and innovative policy approaches to secure equitable access and availability of medical countermeasures. Taking into account different methodologies and approaches to adult learning, a set of complementary training activities are implemented, aimed at strengthening individual capacities (like eLearning, thematic workshops or support to communities of practice) and at encouraging organisational development and improvement (like simulation exercises and an exchange programme). Additionally, HERA will also consider the possibility of funding and supporting the organisation of trainings and/or participation of Member States in training actions developed by the relevant stakeholders, like the World Health Organization.

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

This action supports the policy priority to be better prepared to respond to cross-border health threats. It contributes to the achievement of the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA/HERA

CP-p-25-42 Study on the implementation of the monitoring framework of the EU One Health Action Plans against AMR and Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach

Antimicrobial Resistance ('AMR') remains one of the major threats to health and continues to be a priority for the new Commission. It is estimated that more than 35 000 people die each year in the EU/EEA as a direct consequence of an infection due to bacteria resistant to antibiotics. AMR has serious human health and economic consequences for healthcare systems. By reducing the ability to prevent and treat infectious diseases, AMR threatens inter alia the ability to perform surgery, the treatment of immunocompromised patients, organ transplantation and cancer therapy. It results in high costs to the healthcare systems of EU/EEA countries. AMR is also a threat to food safety and food security as it has an impact on animal health and production systems. This is why in June 2023; the Council adopted the

Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach[120] (the 'Council Recommendation'). The Council Recommendation extends and complements the European One Health Action Plan against AMR[121] (the '2017 AMR Action Plan'), in all three dimensions of the One Health spectrum (human, animal, and environmental). As outlined in the Council Recommendation, the Commission developed a cost-effective monitoring framework to assess the progress and results achieved in implementing the 2017 AMR Action Plan and the AMR Council Recommendation. This monitoring framework will be used, as a main input, to report back to the Council in 2027, four years after adoption of the Council Recommendation on AMR.

The objective of this action is to allow for the monitoring of the progress and results achieved in implementing the Council Recommendation on AMR and the 2017 AMR Action Plan.

The geographical scope of the study is all EU-27 Member States/EEA. The study should cover One Health actions to curb AMR, encompassing the human health, animal health, plant health and the environmental sectors, taken at Member State level as well as at Union level, as reflected in the monitoring framework.

The activities include implementation of the already designed monitoring framework to:

1. populate a set of indicators for which the information is not yet routinely collected or reported, with baseline data for the year 2023;
2. update data for the entire set of indicators of the monitoring framework for the year 2026; and
3. use data from the whole set of indicators to analyse the progress and results achieved between 2023 and 2026.

The expected result of the action is the full implementation of the AMR monitoring framework. Ultimately, this strongly contributes to ensuring the effectiveness of the actions outlined in the Council Recommendation and the 2017 AMR Action Plan and their relevance for addressing AMR, as well as Member States and stakeholders' awareness of the progress achieved. This will also identify potential gaps and areas where further efforts might be needed.

The populated monitoring framework will support the Commission in reporting back to the Council in 2027.

This action contributes to the achievement of the EU4Health Programme's general objectives of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare; and 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, points (a) and (b), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (b) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tenders (service contract), service contract using an existing framework contract.

Indicative budget for this thematic area: EUR 250 000

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120 Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01 OJ C 220, 22.6.2023, p. 1–20.

121 A European One Health Action Plan against Antimicrobial Resistance.

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1. TOBACCO POLICY

DP-p-25-43 Operation of IT databases under the Tobacco Products Directive

The Tobacco Products Directive[122] provided the legal basis for the operation of two comprehensive reporting and monitoring systems for tobacco and related products and their tracing. In this respect, the Commission has been given specific tasks in running and/or monitoring of these systems.

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

a) operation and development the EU Common Entry Gate ('EUCEG') product database;
b) monitoring and oversight of the tobacco tracking and tracing system.

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

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

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

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

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

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: DG SANTE

DP-p-25-44 Operation of technical group for characterising flavours under Directive 2014/40/EU

The implementation of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products[123] entails the operation of a technical group of sensory and chemical assessors ('the technical group') assisting the Independent Advisory Panel ('IAP') in determining whether tobacco products impart a characterising flavour in cigarettes and roll-your-own tobacco, and heated tobacco products.

The general objective of this specific contract is to provide scientific, economic and technical expertise to facilitate the implementation of the current tobacco control policies. More specifically, it should provide input to the assessment of sensory profiles and, where appropriate, chemical properties of tobacco products with a view to assist in decisions on whether tobacco products impart a characterising flavour other than tobacco. To reach these

122 Directive 2014/40/EU
123 ELI: http://data.europa.eu/eli/dir/2014/40/oj.

objectives, the contractor will be responsible for maintaining the technical group of sensory and chemical assessors as specified in Article 12(1) of Implementing Decision (EU) 2016/786). The reports from the contractor are essential for the Independent Advisory Panel to support decisions and replies to the requests from Member States.

The activity will cover the operation of the procedure for the period 2026 - 2027 for determination whether tobacco products impart a characterising flavour (IAP + the technical group), in particular:

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

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

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

Indicative budget for this thematic area: EUR 610 000

Implementation by: HaDEA

2.2. EUROPEAN REFERENCE NETWORKS

DP-p-25-45 Union level event on patients' rights in cross-border healthcare and the European Reference Networks

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[124] lays down patients' rights in cross-border healthcare and the European Reference Networks for rare and complex diseases. According to the last report (May 2022) on the implementation of the Directive, Unioncitizens[125] are still not well informed about their rights on cross-border healthcare, therefore a follow-up action was recommended to raise awareness on patient's rights including the European Reference Networks ('ERNs') among patients, patient organisations and health professionals. This also facilitates the integration of the ERNs into the national health care systems.

In 2024, the Commission, in collaboration with the National Contact Points for cross-border healthcare, customised and improved communication materials and organised a series of 10 workshops at national level. Taking stock of these workshops, a Union-level event will take place in 2025 presenting the outcomes of the national workshops and newly prepared communication material, thus further raising awareness on patients' rights in cross-border healthcare and the European Reference Networks for rare disease.

This EU-level event will contribute to give more visibility to key Union projects making a difference to people and embedding citizen participation in the work of the Union. It will be a one-day event delivered in hybrid format targeting selected stakeholders (Member States, policy makers, health insurances, health care providers, health professionals, patient's organisations) about 150 on site participants and 500 online participants. Organising a Unionlevel event is crucial to raise citizens' awareness, promote active participation, and bridge the gap between policy efforts and public understanding, fostering a more inclusive approach to addressing implementation of the cross-border health care Directive including the European Reference Networks.

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

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

Indicative budget for this thematic area: EUR 80 000

Implementation by: HaDEA

DP-p-25-46 Amendment to the European Reference Networks Evaluation Methodology

According to Commission Implementing Decision 2014/287/EU[126], all networks and their members must be periodically evaluated by a Commission-appointed body at least five years after their approval or last evaluation and every five years after that, if applicable. The evaluation process and methodology are based on Implementing Decision 2014/287/EU, as

124 http://data.europa.eu/eli/dir/2011/24/2014-01-01.
125 http://data.europa.eu/eli/dir/2011/24/2014-01-01.
126 http://data.europa.eu/eli/dec_impl/2014/287/2019-08-18.

specified by the Evaluation Manual and the Toolbox. A follow-up action after the completion of the first evaluation in 2023, was to improve the evaluation methodology. The European Reference Network Coordinators Group as well as the Board of Member States support the need to revise the evaluation methodology.

This action will provide the Commission with a revised evaluation methodology reducing the administrative burden for the European Reference Networks while enabling a high-quality evaluation. The European Reference Network Coordinators Group as well as the Board of Member States support the need to revise the evaluation methodology. The evaluation process and methodology are based on Implementing Decision 2014/287/EU, as specified by the Evaluation Manual and the Toolbox.

An improved evaluation methodology is expected which will be used in the next evaluation cycle for the European Reference Networks. It will be based on lessons learned from the first evaluation cycle completed in 2023 and aims to improve the methodology and process for the future.

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

Indicative type of contracts/supply: open call for tenders (service contract).

Indicative budget for this thematic area: EUR 400 000

Implementation by: HaDEA

DP-p-25-47 Health Policy Platform

DG SANTE has built up good collaboration and communication channels with its health stakeholders to contribute to health policy development. In 2016, the Health Policy Platform was launched. It provides a framework and IT-infrastructure for an improved, more interactive and more outcome-oriented communication between the Commission and its stakeholders and between the stakeholders themselves. It is now open to all stakeholders across the Union.

It therefore supports the implementation of the Commission's role to promote the coordination of and collaboration between the Member States in the area of public health.

By fostering stakeholder engagement, the Union ensures that policies are well-informed, widely supported, and effectively implemented, ultimately leading to better outcomes for all Member States.

This action is expected to:

- strengthen health policy based on coordinated input from health stakeholders and better instruments for collaboration of Commission expert and stakeholder groups;
- improve possibilities for stakeholders to develop joint position statements and communicate them to DG SANTE;
- improve input from stakeholders supporting DG SANTE in acquiring country knowledge and performing its policy work;
- enable more efficient work within Commission expert and stakeholder groups due to better communication between meetings.

The Platform continues to prove being a very reactive, solid and transparent support to active collaboration between the Commission and concerned stakeholders also in case of emergencies

(the COVID-19 pandemic, the Ukraine refugees' crisis with help to neighbouring Member States and Moldova).

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

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

Indicative budget for this thematic area: EUR 525 000

Implementation by: HaDEA/DG SANTE

3. CANCER, CARDIOVASCULAR AND OTHER NON-COMMUNICABLE DISEASES (CR/CV&NCDs)

CR/CV&NCDs-p-25-48 Europe's Beating Cancer Plan annual event and administrative support to the plan's governance mechanism and stakeholder engagement

Europe's Beating Cancer Plan, presented in February 2021, is built around ten flagship initiatives, including those implemented through the EU Cancer Mission, and several other actions. It supports Member States' work to prevent cancer and to ensure a high quality of life for cancer patients, survivors, their families and carers and is structured around a number of key areas where the Union can add most value:

- prevention
- early detection
- diagnosis and treatment
- quality of life of cancer patients and survivors

The purpose of this action is to provide administrative and logistical support services to DG SANTE in organising the annual stakeholder event and to support the continued implementation of the plan by providing administrative support to the governance mechanism and stakeholder engagement. This event, for which 50% of the action's budget is earmarked, is gathering participants in person and online, allows the Commission to reach out to the stakeholders and to showcase the progress made for the implementation of the Europe's Beating Cancer Plan.

In addition, 50% of the budget of this action covers additional support services for SANTE in the area of communication, outreach to stakeholders and information dissemination including for the governance mechanism of the plan.

The result will be an event where Member States and relevant health stakeholders can learn about the achievements, implementation of the Cancer Plan, as well as the EU Cancer Mission, and the proposed way forward, as well as aid the continued implementation of the plan as outline in the mission letter for the new mandate.

The results for the support services will be the production of communication assets and their targeted dissemination through the already established communication channels of the three different governance groups of the Cancer Plan: Member States, stakeholders and the inter-service group.

This action implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (a), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 200 000

Implementation by: HaDEA/DG SANTE

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

4.1. IMPLEMENTATION OF REGULATION ON HEALTH TECHNOLOGY ASSESSMENT

HS-p-25-50 Continuous development and maintenance of the HTA IT platform

Regulation (EU) 2021/2282[127] was adopted on 15 December 2021 and entered into force on 11 January 2022. It applies from 12 January 2025, starting with medicinal products for the treatment of cancer and advanced therapy medicinal products.

Regulation (EU) 2021/2282 focuses on clinical aspects of health technology assessment ('HTA') and provides a permanent legal framework for the conduct at the Union level of joint clinical assessments, joint scientific consultations, the identification of emerging health technologies and joint work on methodologies.

It provides for a governance system made of a Member State Coordination Group (the 'HTACG'), four different subgroups covering the main activities above, and a Stakeholder Network. The Commission provides the Secretariat for this structure.

This action supports the implementation of Regulation (EU) 2021/2282 in 2025, in particular its Article 30 on the set up and maintenance of an IT platform to perform the joint work on HTA.

The HTA IT Platform will consist of a public page and a secure intranet for the exchange of information between members of the HTACG and its subgroups, and with health technology developers and experts, with the European Medicines Agency and the Medical Device Coordination Group, as well as between members of the Stakeholder Network.

The main features of the IT Platform, in particular the set-up of a secure intranet for the work on the joint clinical assessment and the joint scientific consultation of medicines will be up and running by 12 January 2025.

However, the complete requirements for the new infrastructure development include for example the work on the joint clinical assessment and the joint scientific consultation of medical devices, as well as the automated system to ensure interoperability with the European Medicines Agency. These will need to be further developed as of 2025. A dedicated publicly accessible webpage is also envisaged to be created in 2025, as during the preparatory phase (2022-2024) the Commission Europa page was used to this end.

The IT Platform itself will need to be maintained and additional activities added to the project following the exponential development of the joint work, for example on IT support, training, user friendliness of the system, etc.

This action will result in full set up and continuous maintenance, including updates, of the HTA IT Platform.

The HTA IT Platform will allow the implementation of joint work on medicinal products under Regulation (EU) 2021/2282, in parallel to the marketing authorisation process. This is expected to contribute to an increased accessibility to efficient medicaments in the Union.

This action implements the EU4Health Programme's general objective of strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of

[127] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).

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

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

Indicative budget for this thematic area: EUR 3 000 000

Implementation by: SANTE

HS-p-25-51 Support to the Secretariat of the Member State Coordination Group on Health Technology Assessment

Regulation (EU) 2021/2282[128] was adopted on 15 December 2021 and entered into force on 11 January 2022. It applies from 12 January 2025, starting with medicinal products for the treatment of cancer and advanced therapy medicinal products.

Regulation (EU) 2021/2282 focuses on clinical aspects of health technology assessment ('HTA') and provides a permanent legal framework for the conduct at the Union level of joint clinical assessments, joint scientific consultations, the identification of emerging health technologies and joint work on methodologies.

It provides for a governance system made up of the Member State Coordination Group (the 'HTACG'), four different subgroups covering the main activities above, and a Stakeholder Network. The Commission provides the Secretariat for this structure.

The purpose of this request is to provide support services to DG SANTE in its role as Secretariat of the HTACG. The HTACG Secretariat has the responsibility to host in the Commission premises the meetings of the HTACG and its subgroups, as well as to provide administrative support to all groups and sub-groups for 2026 and 2027 included.

The HTACG has established subgroups for joint clinical assessments, joint scientific consultations, identification of emerging health technologies, development of methodological and procedural guidance.

Additional subgroups or working groups may be established. For example, a HTA IT platform users working group was set up to ensure the involvement of users in the development of the HTA IT platform.

The Commission has also created a Stakeholder Network to support the work of the HTACG and its subgroups upon request. That Stakeholder Network will meet at least once each year.

In the context of all these groups, subgroups and networks, the activities requested are, for example, administrative coordination of the meetings, preparation of the relevant documents, welcome desk and registration, organisation of the catering. For the meetings of the Stakeholder Network the services will also include the identification of a suitable venue as well as the organisation and payment of travel and accommodation for participants.

The proposed action will contribute to the implementation of annual work programmes of the HTACG, including the organisation of meetings of the HTACG, its subgroups and the Stakeholder Network. The number of meetings will be defined by the Coordination Group on an annual basis.

[128] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).

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

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

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

HS-p-25-52 Supporting joint work of Member States in the field of Health Technology Assessment

Regulation (EU) 2021/2282[129] was adopted on 15 December 2021 and entered into force on 11 January 2022. It applies from 12 January 2025, starting with medicinal products for the treatment of cancer and advanced therapy medicinal products.

Regulation (EU) 2021/2282 established the Member State Coordination Group (the 'HTACG') and four subgroups. The nominated members of the HTACG and its subgroups are predominantly representatives of the HTA agencies from the respective Member States. These are mainly public authorities or work under the guidance of public authorities.

In line with the very specific governance structure under Regulation (EU) 2021/2282, an important part of the Member States' joint work consists of conducting Joint Clinical Assessments ('JCA') and Joint Scientific Consultations ('JSC').

The objective of this action is to support the members of the HTACG and its subgroups to conduct joint work as stipulated in Regulation (EU) 2021/2282, i.e., JCA and JSC.

The scope and requirements of the joint work are defined by Regulation (EU) 2021/2282. This also includes the involvement of patients, clinical experts, and other experts.

With respect to JCA and JSC a staggered approach will apply: the members of the HTACG and its subgroups will conduct JCA and JSC based on the HTACG annual work programmes and apply methods and guidance developed by the HTACG and its subgroups.

JCA to be funded under this action are for:

- applications for marketing authorisations of new medicinal products for the treatment of cancer and advanced therapy medicinal products;
- application for a variation to the terms of an existing marketing authorisation for a new therapeutic indication of the medicinal product;
- selected high-risk medical devices and in vitro diagnostic medical devices (based on a recommendation of the HTACG).

JSC to be funded under this action can be conducted on medicines, medical devices or in vitro diagnostic medical devices as a JSC HTA process only or in parallel with a scientific advice procedure at EMA/consultation of the expert panels on medical devices.

The JSC and JCA will be funded based on the work programmes of the HTACG and the availability of funding.

[129] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).

The outcomes of this action will be the production of high-quality reports and summary reports for JCA as well as well as outcome documents for JSC for medicinal products and medical devices and in vitro diagnostic medical devices in scope of Regulation (EU) 2021/2282.

The JCA and JSC to be conducted by the members of the HTACG and its subgroups will cover the clinical dimensions of the HTA domains. This will provide Union added value by enhancing convergence among the Member States' practices to support high-quality and evidence-based decision-making, while ensuring transparency and inclusiveness by involving relevant experts. This joint work produced at the Union level will support the Member States to draw conclusions on the added value of specific products for their health systems and help them take decisions on pricing and reimbursement of medicinal products and medical devices 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 (c), (h) and (i), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 7 300 000

Implementation by: HaDEA

4.2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND PHARMACEUTICAL STRATEGY

HS-p-25-53 Implementation of the pharmaceutical legislation and data-driven policy for medical products

Evidence-based and data-driven policy making is at the heart of the Commission's better regulation agenda, and the sector of medical products (pharmaceuticals and medical devices) is no exception to that. The sector plays a critical role in providing healthcare for the Union population and is a major contributor to the Union's competitiveness. Therefore, it is necessary that the Commission has access to sector specific data at the Union and national level, as well as on therapeutic area and medical product level, together with the necessary capacities to analyse, present and visualise them.

The COVID-19 pandemic and the evaluation and impact assessment exercise accompanying the revision of the Union pharmaceutical legislation demonstrated that good data on the sector exist and are extremely valuable for policy makers. However, the data is scattered and difficult to interpret, the analysis of which requires specific expertise on the databases and on the functioning of the sector. It has been difficult and time-consuming to retrieve the information needed to support the policy actions. The lessons learned from these exercises are that a permanent structure that allows quick access to data and analytics, tailor-made to the needs of the Commission is needed.

Under the 2024 EU4Health work programme, action HS-p-24-50, a framework contract to support the Commission in setting up an evidence-based and data-driven policy making framework was programmed. This action foresees to continue providing funding to the above framework contract, which is expected to run until 2028. It will support the work on the reform of the pharmaceutical legislation and its subsequent implementation, which is one of the priorities outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare.

The objectives of this action are to:

a) provide impartial economic and market analysis in the area of pharmaceuticals and medical devices. These analyses will support the Commission to enhance the factual foundation of policymaking for example during the negotiations or in the preparation of secondary and tertiary legislation in the area of pharmaceuticals and medical devices;
b) provide scientifically based data analytics including, for example, of firm-level data, market/sales data, financial data, clinical trials/performance studies/clinical investigations activity, sectoral/company account data, as well as large data sets on characteristics of medical products. The tasks include the collection and procession/cleaning/management of quantitative and qualitative data as well as the visual presentation of (aggregate) data;
c) provide economic analysis with appropriate state-of-the-art descriptive statistics and quantitative techniques, such as, if necessary, linear and non-linear regression models, time series analysis, forecasting models;
d) identify trends within the medical products sector for the Commission, using quantitative methods if appropriate, to anticipate potential future needs and developments and use this foresight to inform potential policy actions;
e) support the Commission in implementing the Pharmaceutical Strategy for Europe and monitoring the impact of applying related policies and legislation as well as legislation

on medical devices and in vitro medical devices, using quantitative methods if appropriate;

f) provide market analysis concerning the various medical products, including the use of technologies, materials and substances in the different manufacturing stages and in end products, as well as the regulatory and economic impact of changes in other legislation on this sector (using quantitative methods if appropriate);
g) monitor the implementation of legislations in the medical products field considering indicators and/or respective objectives;
h) develop appropriate key performance indicators to monitor the impact of changes in relevant policies and legislation.

This proposed action will continue supporting activities procured through the framework contract concluded under the 2024 EU4Health work programme (to implement action HS-p-24-50), with the objective of procuring timely and high-quality services to support data-driven policy for medical products.

These activities will be carried out through two streams of work:

1. a permanent collaboration based on pre-set deliverables, such as briefs and reports covering different aspects of the medicinal products (innovation, access, affordability, or competitiveness);
2. ad-hoc requests requiring prompt replies. The work would entail fast analyses that would be delivered in a matter of a few weeks.

The contracts for services would cover a broad scope of health interventions, with a primary focus being on medicinal products, and medical technologies. They will also allow to have updates landscape analysis of specific therapeutic sectors, such as oncology where both medicinal products and medical devices are key for the treatment of patients. Such a combined approach would be an important step of overcoming the segmentation of the medical products sector and allow for a better insight into health innovations.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, 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, points (c) and (h), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: total estimated ceiling of the framework contract is EUR 6 000 000. Total estimated consumption for 2025 is EUR 1 000 000 for direct service contract(s).

Implementation by: DG SANTE and HaDEA

HS-p-25-54 Preparation for the implementation of the reform of the Union pharmaceutical legislation

On 26 April 2023, the Commission proposed an ambitious reform of the pharmaceutical legislation. The revision includes proposals for a new Directive[130] and a new Regulation[131], which revise and replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases.

This revision aims to achieve the following main objectives:

a) creating a Single Market for medicines ensuring that all patients across the Union have timely and equitable access to safe, effective, and affordable medicines;
b) setting up an attractive and innovation-friendly regulatory framework for research, development, and production of medicines in Europe;
c) reducing the administrative burden by speeding up procedures significantly;
d) enhancing availability and ensuring medicines can always be supplied to patients, regardless of where they live in the Union;
e) addressing antimicrobial resistance and the presence of pharmaceuticals in the environment through a One Health approach;
f) making medicines environmentally more sustainable.

The reform is currently being negotiated by the co-legislators. During this period, several preparatory actions would need to be initiated to ensure quick implementation of the legislative proposals once they are agreed by the co-legislators.

Objective of this action is to ensure that once agreed by the co-legislators, the revised pharmaceutical legislation will be operational in a timely manner.

To achieve this objective, studies and other actions should be funded to support the preparatory work for the implementation of certain technical provisions foreseen by the reform of the pharmaceutical legislation.

For example, actions could be requested to support the Commission for:

- setting up of platforms for data related to specific medicinal product technologies;
- setting up and functioning of multistakeholder consultative groups;
- horizon scanning and analysis of possible areas where an adapted legislative framework would be needed (for example phage-containing medicinal products or anticancer treatments based on particular innovative technologies);
- setting up pilot studies to test how to best put in application novel concepts introduced with the reform of the pharmaceutical legislation.

The expected result of this action is to collect the necessary information to put in place procedures for the implementation of certain provisions included in the proposals for the revision of the pharmaceutical legislation.

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130 Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM/2023/192 final).

131 Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM/2023/193 final).

The action supports the implementation of Union pharmaceutical legislation, which is one of the priorities outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare and it implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tenders (service contract), use of existing framework contract.

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA/DG SANTE

HS-p-25-55 IT support to the European Medicinal Products database

The purpose of the European Medicinal Products (the 'EMP') database is to support DG SANTE with creation, maintenance, amendment, suspension, or withdrawal of medicinal products centralised marketing authorisation on the basis of the scientific opinions received from the European Medicines Agency. Such authorisations are granted by the Commission for all new active substances (for example novel anti-cancer treatments), innovative and orphan medicinal products, and are valid for all the EU/EEA. To this purpose, the information system is constantly updated to maintain its efficiency and the quality of its outputs.

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

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

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

Indicative budget for this thematic area: EUR 450 000

Implementation by: DG SANTE

HS-p-25-56 Study on the application of Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Regulation (EU) 2022/123[132] strengthens the role of the European Medicines Agency (the 'EMA') in crisis preparedness and the management of medicinal products and medical devices, allowing the EMA to closely monitor and mitigate shortages of medicines and critical medical devices and facilitate faster approval of medicines that could treat or prevent a disease causing a public health crisis.

[132] 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, 31/01/2022, p. 1).

Article 36 of Regulation (EU) 2022/123 requires the Commission to present by 31 December 2026 a report to the European Parliament and the Council on the application of Regulation (EU) 2022/123 and following a public health emergency or a major event. To ensure timely presentation of the report, the study which will support it must be launched in 2025.

The report shall contain a review of:

a) the crisis preparedness and management framework for medicinal products and medical devices, including the outcomes of periodic stress tests;
b) instances of non-compliance with the obligations set out in Article 10 and Article 26 of Regulation (EU) 2022/123 by marketing authorisation holders, manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies;
c) the remit and functioning of the European Shortages Monitoring Platform (the 'ESMP').

Based on this report, the Commission shall, where appropriate, present a legislative proposal in order to amend Regulation (EU) 2022/123, considering in particular the need for extending the scope of Regulation (EU) 2022/123 to veterinary medicinal products and to personal protective equipment for medical use, amending Article 2, introducing measures to strengthen at Union or national level compliance with the obligations established in Articles 10 and 26, of Regulation (EU) 2022/123 and expanding the remit of the ESMP, the need for further facilitating the ESMP interoperability with national and the Union IT systems, the need for national shortage monitoring platforms, and the need for meeting any additional requirements to address structural shortages of medicinal products that may be introduced in the context of a revision of Directive 2001/83/EC[133] and Regulation (EC) No 726/2004.[134]

The objective of this action is to conduct a study that will prepare the report on the application of the EMA extended mandate.

The contractor will gather and analyse data and feedback from all interested parties (the EMA, National Competent Authorities, Marketing Authorisation Holders, patients, etc.) to review:

a) the crisis preparedness and management framework for medicinal products and medical devices, including the outcomes of periodic stress tests;
b) instances of non-compliance with the obligations set out in Article 10 and Article 26 of Regulation (EU) 2022/123 by marketing authorisation holders, manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies, including for the COVID-19 and Mpox public health emergencies;
c) the remit and functioning of the ESMP.

The contractor will organise and conduct bilateral interviews and workshops to collect the views from all stakeholders on the EMA extended mandate, how it is implemented and what can be improved.

The contractor will provide a study report for this activity, which will be used by the Commission to prepare the reports requested by Article 36 of Regulation (EU) 2022/123. This analysis of the implementation of Regulation (EU) 2022/123 is instrumental to optimise its application.

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133 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 L 311, 28/11/2001, p. 67).

134 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

The action supports the reform and implementation of the Union's pharmaceutical legislation, which is one of the priorities outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare and it implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 400 000

Implementation by: HaDEA

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

HS-p-25-26 Support and facilitate the implementation of the SoHO regulation, including dissemination and training of SoHO professionals

Regulation (EU) 2024/1938[135] brings many new requirements, both for stakeholders on how to organise safety and quality, and for authorities on how to organise oversight, in particular:

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

This action is essential to prepare SoHO professionals across the Union for the implementation of Regulation (EU) 2024/1938 by 2027.

The contractor(s) will be responsible for:

- organising awareness building and training tools and activities for SoHO professionals across the Union;
- providing advisory capacity and technical assistance to support SoHO professionals with specific needs during the implementation of Regulation (EU) 2024/1938;
- preparing a repository of support documents (sets of questions and answers) for professionals in SoHO sub-sectors;
- analysing specific implementation issues and proposal to overcome the concerns and questions raised by the different subgroups of SoHO professionals, support SoHO

[135] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024).

professional with the implementation of procedures on data and evidence collection, or other requirements defined in Regulation (EU) 2024/1938.

This action will support Member States with:

a) reinforced, and more harmonised safety and quality requirements applied by professionals across Member States, this enhancing trust between them and facilitating the exchange of SoHO between the Member States and optimising access for patients;
b) training programme, and repository of training materials, useful for trained staff and new staff in SoHO entities and establishments;
c) inputs for central policy making, through the SoHO Coordination Board and for guideline development in the expert bodies.

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

Indicative type of contracts/supply: open call for tenders (service contract).

Indicative budget for this thematic area: EUR 3 500 000

Implementation by: HaDEA

HS-p-25-57 Development of SoHO digital platform (SoHO-X)

Chapter XI of Regulation (EU) 2024/1938[136] calls on the Commission to set, manage, and maintain a substances of human origin ('SoHO') platform[137] to facilitate exchange of information concerning SoHO activities in the Union.

This platform will support provisions under different other chapters of SoHO Regulation, including:

a) registration of entities, publication of registered entities and their possible authorisation status (preparation, import, establishments);
b) activity data reporting;
c) vigilance reporting of serious adverse reactions/events, and of rapid alerts;
d) traceability and coding;
e) publication of technical guidelines;
f) information exchange between authorities across the Union;
g) publication of Union level advice of the SoHO Coordination Board.

The SoHO digital platform will significantly facilitate exchange, management, and consolidation of data based on a common vocabulary and providing interoperable machine to machine interfaces, using open source whenever possible. It will consequently also allow to prepare and publish reports, at national level as well as at Union level.

Significant groups of SoHO are essential for cancer treatment, like blood transfusions in oncology, or bone marrow transplants (haematopoietic stem cells) to cure blood cancers like

136 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024).

137 IT development and procurement strategy choices will be subject to pre-approval by the European Commission Information Technology and Cybersecurity Board.

lymphoma or leukaemia, or fertility preservation for children risking losing fertility due to chemotherapy.

This action is essential to prepare for the implementation of Regulation (EU) 2024/1938 by 2027. The objective of this action is to be ready by 2027 with the implementation of the obligations of Regulation (EU) 2024/1938. The scope of the action is the development of the first version of the SoHO platform, covering at least the "Minimum Viable Product", defined as the legal requirements of Regulation (EU) 2024/1938, and extra necessary features that have been clarified by pre-existing analysis work.

The key activities include the development of several functional capabilities required to support the SoHO digital platform and the interoperability with other information systems.

a) Registration capability. This capability is needed to support several provisions like entity registration and authorisation of preparation processes.
b) Publication. This capability is needed to publish a list of registered entities, authorised establishments, technical standards, or contact details.
c) Reporting and monitoring. This capability will allow to report, collect, and monitor activity data as well as vigilance data.
d) Notifications and alerts. This capability will allow the managing of safety alerts (serious adverse occurrences) as well as supply alerts.
e) Collaborative space. This capability increases the efficiency of work in each of the national authorities, allowing them to quickly retrieve contacts and expertise in peer authorities.

This action is expected to result in:

a) smooth data collection and reporting on activities and on vigilance;
b) facilitated monitoring and communication of safety alerts;
c) facilitated monitoring and communication of supply shortages;
d) Union-wide transparency on active entities, authorised establishments, importing entities, authorised SoHO preparations and on local/national authorities overseeing the sector;
e) Union-wide transparency on applicability of the SoHO framework and of the technical guidelines to be followed by professionals performing SoHO activities;
f) a collaborative space and common guidance for oversight practices for and between the national and local authorities;
g) consolidated Union level view on supply and safety of different SoHO;
h) increased capacities with professionals, in SoHO entities/establishments, as well as in testing laboratories, to comply with Union level requirements on safety and quality.

This action supports the implementation of the new legislative framework for substances of human origin, and it implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (h), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: DG SANTE

HS-p-25-58 Supporting joint work of Member States in the field of substances of human origin (SoHO)

Regulation (EU) 2024/1938[138] established the SoHO Coordination Board ('SCB') and specifies the delegation of tasks to working groups. The nominated members and alternates of the SCB and its working groups are representatives of the SoHO national authority and, where the Member State chooses so, the Ministry of Health or other relevant authorities, or delegated bodies. These are public authorities or work under the guidance of public authorities.

Article 69(1) Regulation (EU) 2024/1938 lays down the tasks of the SCB and its working groups. The objective of this action is to support the members of the SCB and its working groups to conduct the joint work as stipulated in Regulation (EU) 2024/1938.

Different tasks will need to be covered, in function of evolving needs and progress in the SCB and its working groups. For example, the following tasks can be covered by this action:

a) technical assessment of Preparation Process Dossiers of new SoHO preparations,
b) development of harmonised guidelines, for example:
    - to define criteria for reporting serious adverse reactions and events,
    - to define criteria for inspections (best practices, training, necessity, risk-based inspection frequency),
    - for the assessment of clinical outcome data,
    - on standardised processes for traceability requirements,
    - for donor data protection.
c) harmonised awareness building for new SoHO entities (e.g. human milk, microbiota, testing labs, clinical users).
d) drafting of opinions on classification of innovative SoHO.
e) identification of training needs for inspectors, assessors and vigilance officers.
f) development of best practices, for example:
    - for handling rapid alerts.
    - for implementation of SoHO supervisory activities.

An estimated number of tasks expected to be covered by this action is between 35 to 40. Usually, these tasks are taken forward by two members of the SCB or its workgroups. An expected workload will be specified per task by the secretariat of the SCB and its working groups.

The outcomes of this action will be the production of high-quality guidelines and opinions, developed by members of the SCB and its working groups, leading to common progress, and eventually a higher level of harmonisation in the Union with respect to quality and safety of SoHO. This will provide Union added value by enhancing convergence among the Member States' practices in relation to SoHO, while ensuring transparency and inclusiveness by involving relevant experts.

This joint work produced at the Union level will support the Member States to ensure a continued provision of SoHO therapies based on high safety and quality standards and up-to-date technical rules in their country, to extend protective measures to patients and donors, to improve harmonisation across Member States, facilitating cross-border exchange of SoHO and

138 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024).

improving patient access to the therapies they need, improve crisis preparedness and resilience to safeguard access to therapies.

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

Indicative type of contracts/supply: The Commission plans to launch an open procedure for a new framework contract or a service contract.

Indicative budget for this thematic area: Total estimated amount of the Framework contract is EUR 4 000 000. Total estimated consumption is EUR 1 000 000 for service contract(s).

Implementation by: HaDEA

HS-p-25-59 Strengthening national implementation of organ transplant practices, in particular through cooperation between national authorities and professional sector associations

The overall aim of this action is to strengthen safety, quality and access to organ transplantation. The sector has been heavily impacted by the COVID-19 pandemic and the levels of organ donation and transplantation are still lower in various Member States as compared to activities before the pandemic.

The objective is to support studies to understand obstacles faced to implement best practices for organ donation and transplantation, analyse how these could be overcome, and to support implementation of targeted actions for exchanging best practices.

The study would cover several successive tasks:

a) expert audit to identify obstacles, barriers and bottlenecks to applying existing best practices, at national level and within healthcare settings, and analysis and proposals for solutions;
b) targeted activities, such as twinning, visits etc. based on the outcome of the first phase, to support overcoming obstacles identified;
c) communication and awareness building of the public to make donations. This can include development, exchange and implementation of good practices like campaigns, use of social media, and similar activities;
d) optimisation of allocation of the limited supply of organs to patients in need. The increasing availability of different sources of organs (e.g., from living donors, paired donor-recipients, from donors after cardiac death, from extended donor criteria donors, etc.) and the use of new technologies to improve transport and quality of organs brings new possibilities for patients. However, this also causes new challenges to ensure optimisation of allocation decisions and needs algorithms that support such decisions. Increasing possibilities for cross-border exchange of organs add to this complexity;
e) Other areas can be proposed in function of the priorities identified by the national transplant services.

These, and other aspects of organ transplantation fall under national mandate and organisation. Nevertheless, the national authorities highly value mutual support and collaboration for their national activities.

This action is expected to result in:

a) increased uptake of best practices for organ donation and transplantation;
b) increased number of organs available for transplantation;
c) increased number of organ transplantation carried out;
d) better access for patients in waiting lists for organ transplantation.

This action supports the implementation of the new legislative framework for substances of human origin, and it implements the EU4Health Programme's general objective of strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (g), (h) and (i), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tenders (service contract).

Indicative budget for this thematic area: EUR 2 000 000

Implementation by: HaDEA

HS-p-25-60 Implementation of the SoHO Regulation: training and networking of SoHO Competent Authorities' staff for oversight

Regulation (EU) 2024/1938[139] brings many new requirements, both for stakeholders on how to organise safety and quality, and for authorities on how to organise oversight, in particular:

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

Regulation (EU) 2024/1938 entered into force in 2024 and will become applicable in 2027. There is a need to support the sector, both competent authorities in the Member States, and stakeholders, to be ready for the implementation of Regulation (EU) 2024/1938.

Significant groups of SoHO are essential for cancer treatment, like blood transfusions in oncology, or bone marrow transplants (haematopoietic stem cells) to cure blood cancers like lymphoma or leukaemia, or fertility preservation for children risking losing fertility due to chemotherapy.

This action is essential to prepare for the implementation of Regulation (EU) 2024/1938 by 2027.

139 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024).

Objective of this action is to organise training and networking activities for Competent Authorities' staff, in particular inspectors, vigilance officers, process assessors, for strengthening the implementation of oversight in the field of SoHO.

The training programme should comprise blended learning, with on-site training courses (three per year, for around 50 people each) with practical cases (exercises) each combined with an e-learning course. The project should also provide an IT platform for exchange of experience among the network and serving as a repository of training material. Basic and advanced training should be provided.

The basic training will increase and standardise the competences of inspectors, vigilance officers and assessors of SoHO preparations in the SoHO sector across the Union. The advanced training will enable building a network of senior inspectors and assessors, facilitating possible joint inspections, peer audits or joint assessments of SoHO preparations among the Member States, and reinforcing trust between them to facilitate the exchange of SoHO.

This action should be a follow-up of the current procurement "Service Contract for Training and Networking of Substances of Human Origin (SoHO) Competent Authorities' Staff for Oversight" – action HS-p-17.1 (a) in the 2021EU4Health work programme. The IT platform developed in this previous action shall be re-used.

This action is expected to result in:

a) reinforced, and more harmonised oversight measures applied by the Member States, thus enhancing trust between them and facilitating the exchange of SoHO;
b) training programme, and repository of training materials, useful for trained staff and new staff in competent authorities;
c) network of trained inspectors, vigilance officers and assessors of SoHO preparations;
d) facilitation of cooperation among competent authorities of different Member States for joint inspection, joint assessment of SoHO preparation, and peer audit;
e) facilitation of the sharing of expertise in the network.

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

Indicative type of contracts/supply: the Commission plans to launch an open procedure for a new framework contract and/or service contract(s) or amendment of an existing service contract.

Indicative budget for this thematic area: Total estimated amount of the Framework contract is EUR 4 000 000. Total estimated consumption is EUR 2 000 000 for service contract(s).

Implementation by: HaDEA

4.4. IMPLEMENTATION OF CROSS-BORDER HEALTHCARE DIRECTIVE

HS-p-25-61 Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, yearly data collection on patient's mobility

Data collection exercises on patient mobility in cross-border healthcare have been carried out annually since 2015 using an agreed questionnaire sent out to the Member States. The last evaluation report of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare [140] highlighted large data gaps to assess the wide range of impacts of the Directive. This action aims at ensuring the continuation of the data collection in the Union on patient mobility and improve its coverage and completeness.

Article 20 of Directive 2011/24/EU requires the Commission to periodically report on the operation of the Directive directly to the European Parliament and to the Council. The data used to analyse the operations of the Directive is collected yearly through an annual questionnaire to be compiled by the National Contact Points ('NCPs') of each country involved with the Directive.

As part of the ongoing monitoring linked to the reporting obligation of the Commission, a yearly data collection exercise is carried out related to the operation of the National Contact Points and on patients' mobility.

The purpose of the contract is to assist the Commission in obtaining and processing the questionnaires, collect the data and produce yearly reports of reference years 2024, 2025 and 2026 for its publication including, an overview on trends (for years 2024 to 2026) and conclusions for the next Commission report on the operation of the Directive.

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

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

Indicative budget for this thematic area: EUR 75 000

Implementation by: HaDEA

[140] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022DC0210.

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

HS-p-25-62 Support to EUDAMED

The implementation of Regulation (EU) 2017/745[141] and Regulation (EU) 2017/746[142] is a priority for the Commission, as highlighted in the mission letter of Commission President von der Leyen to the Commissioner for Health and Animal Welfare, the Council Conclusions on the Future of the European Health Union of June 2024 and several debates in the EPSCO Council, the last one in December 2024.

The creation of European database on medical devices **(**'EUDAMED') is one of the key aspects of the medical devices legislative framework. EUDAMED improves transparency and coordination of information regarding medical devices available on the Union market.

This action will support the finalisation of development, improvement and maintenance of EUDAMED. EUDAMED is one of the core elements of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

Its use by economic operators, competent authorities, sponsors of clinical investigations/performance studies and notified bodies is a legal obligation stemming from Regulation (EU) 2017/745 and Regulation (EU) 2017/746, 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 structured around six interconnected modules: Actors registration, Unique Device Identification/ Devices registration, Notified Bodies and Certificates, Clinical Investigations and performance studies, Vigilance and post-market surveillance, Market Surveillance – with the first three already available for voluntary use.

EUDAMED is now in an advanced stage of development and the 2025 EU4Health work programme is supporting the finalisation and maintenance of the first five modules and the continuation of development of the sixth.

This action will contribute to the development and maintenance of EUDAMED, by:

a) supporting the finalisation and improvements of the Actors, UDI/Devices, Notified Bodies and Certificates, Vigilance and post-market surveillance, and Market Surveillance modules, including the post audit phase and the readiness of the modules for their mandatory use;
b) supporting the development of the clinical investigation and performance studies module, for which a number of challenges have been identified, requiring appropriate technical solutions;
c) supporting the independent audit of the vigilance and post-market surveillance module;

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141 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).

142 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).

d) supporting the development of the functional specifications and improvements that were agreed to be developed after EUDAMED minimum viable product delivery, for the modules declared functional;
e) supporting maintenance of the system and providing the necessary user support and technical documentation for the system use.

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

Indicative type of contracts/supply: administrative arrangement, use of an existing framework contract, open call for service contract or negotiated procedure for service contract.

Indicative budget for this thematic area: EUR 4 200 000

Implementation by: HaDEA/DG SANTE

HS-p-25-63 Technical assistance to support the implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 on medical devices and in vitro diagnostic medical devices

Medical devices and *in vitro* diagnostics have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of many diseases, including non-communicable diseases such as cancer, cardiovascular diseases or diabetes.

Regulation (EU) 2017/745[143] and Regulation (EU) 2017/746[144] were adopted in 2017 with the aim to increase patient safety throughout the Union, whilst supporting innovation.

The implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 is a priority for the Commission, as highlighted in the mission letter of Commission President von der Leyen to the Commissioner for Health and Animal Welfare, the Council Conclusions on the Future of the European Health Union of June 2024, and several debates in the EPSCO Council, the last one in December 2024.

As the transition towards the new framework has been slower than anticipated, the transition periods of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 have been extended and many non-legislative actions have been put in place to notably increase the capacity of notified bodies and preparedness of manufacturers.

Today, the implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 is still ongoing, strongly supported by the Commission, the Medical Device Coordination Group, and the Notified Body Coordination Group that all have specific tasks as laid out in Article 104, Article 105 and Article 49 of Regulation (EU) 2017/745. Due to the large scope of activities and the corresponding specialised expertise required of technical, scientific and clinical aspects, it has proven challenging to fulfil some of these provisions.

To further step up the implementation of the current regulatory framework as noted in the mission letter of the Commission President von der Leyen to the Commissioner for Health and Animal Welfare, as well as support the development of actions that help the sector comply with the rules of the regulatory framework, this action intends for an external party to provide technical and administrative support in the setting up and conducting of these actions and manage a group of experts with varying expertise in the medical devices and *in vitro* diagnostic medical devices field that can assist the Commission services and the Medical Device Coordination Group.

The tasks for this external party would include provision of administrative and technical support for coordinating the setting up and conducting of various actions that help the sector comply with the rules of the regulatory framework and contribute to ensuring the interplay with other regulatory frameworks (e.g., providing technical support to notified bodies coordination group, providing administrative and technical support to competent authorities assessment of multinational medicinal product/medical device/in vitro diagnostic combined studies).

The tasks for the group of experts would include:

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143 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).

144 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).

a) conducting market scanning and research on scientific, clinical and technical topics related to notified bodies designated under Regulation (EU) 2017/745 and Regulation (EU) 2017/746, clinical investigations and evaluations, performance studies, clinical investigations/performance studies combining medical devices with a clinical trial of a medicinal product, standards, new and emerging technologies, nomenclature, borderline and classification, market surveillance, post-market surveillance and vigilance, *in vitro* diagnostic medical devices, Annex XVI products, unique device identification, international matters;
b) drafting and providing support to the groups for drafting concept papers and technical documents on a variety of scientific, clinical and technical topics in the field of medical devices and in vitro diagnostic medical devices; and
c) developing trainings and training materials on a variety of scientific, clinical and technical topics in the field of medical devices and *in vitro* diagnostic medical devices.

This action is expected to support and feed into the work of the Medical Devices Coordination Group.

This action is intended to identify measures that could contribute to the reduction of burden and provide clarity to the sector, fostering innovation and competitiveness.

This action is also expected to support the medical devices sector to transition to the rules set out in Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

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

Indicative type of contracts/supply: use of existing or open procedure for a new framework contract.

Indicative budget for this thematic area: EUR 1 250 000

Implementation by: HaDEA/SANTE

HS-p-25-64 Studies supporting better regulation activities in the field of medical devices and in vitro diagnostic medical devices

Medical devices and *in vitro* diagnostics have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of many diseases, including non-communicable diseases such as cancer, cardiovascular diseases or diabetes. Regulation (EU) 2017/745[145] on medical devices and Regulation (EU) 2017/746[146] on *in vitro* diagnostic medical devices were adopted in 2017 with the aim to increase patient safety throughout the EU, whilst supporting innovation.

[145] 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).

[146] 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).

As the transition has been slower than anticipated, the Commission has extended the transition periods of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 several times and has put in place a number of non-legislative actions to support the sector (e.g., actions funded through the EU4Health Programme to increase the capacity of notified bodies and preparedness of manufacturers, providing guidance in collaboration with the Medical Device Coordination Group). In line with the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare, the Commission is committed to evaluate the need for potential legislative changes.

Given the central role of medical devices in the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease and therefore patient care, it is essential that the regulatory framework and the transition towards the rules it sets out is thoroughly assessed and monitored and challenges are addressed based on sound evidence of problems and impacts.

This action aims to support the Commission in assessing and monitoring the regulatory framework of medical devices with a view to possibly addressing some of its shortcomings in an informed way.

The activities under this action include:

a) developing a monitoring framework and defining output and impact indicators relevant for the Regulations on medical devices and *in vitro* diagnostics (Regulation (EU) 2017/745 and Regulation (EU) 2017/746);
b) surveying key actors operating on the market, including notified bodies, economic operators and healthcare professionals to get information on devices and certificates;
c) supporting the Commission in the development of an analysis of impacts of the various policy options which may be proposed in response to the problems identified as a result to the evaluation of the current legal framework.

This action will allow the Commission to monitor the Union regulatory framework on medical devices and the application of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and its performance with a view to proposing informed improvements that contribute to the reduction of burden and provide clarity to the sector, fostering innovation, safety and competitiveness.

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

Indicative type of contracts/supply: Open call for tenders (service contract), open call for tenders (framework contract), use of existing or new framework contract, expert contracts with fees following establishment of/under existing call for expression of interest, including membership fees.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA/DG SANTE

4.6. HEALTH PROFESSIONALS

HS-p-25-65 Programme of Continuous Learning within a European Health Union Professional Network (Health Union Fellowship Programme)

The Union already benefits from diverse stakeholders active in capacity-building for health policy development and implementation in the Union, delivering high-quality training and professional education. These capacity-building entities target a range of policy-relevant expertise and include specialised training programmes such as health law, health economics, and public health. Altogether, they provide a comprehensive coverage of knowledge and through academic collaboration, they provide a research focus. But this remains scattered, and after several decades of excellent output is not fully harnessed. Therefore, there is a need to develop a network of Union health policy makers that shares a profound understanding of the Union health policy and instruments, and a solid basis of interpersonal and professional trust.

The aim of the action is to build, through a continuous capacity building programme, a robust and growing Union network of peers from Ministries of Health and relevant departments across national administrations who can be contacted in case of questions on Union health policies, thereby actively contributing to Union policies and programmes and effectively using Union instruments. The network will include a built-in multiplier mechanism to facilitate the transfer of knowledge and expertise to a broad range of actors.

In 2024, a first cohort of mid-career professionals from Member States' Ministries of Health or other relevant administrations has been enrolled in a one-year supervised learning by doing training programme. The number of fellows in the next cohort (2025/2026) will increase to 54. The network of professionals will not only include the cohort of participants, but also the graduated alumni, their supervisors, training facilitators and stakeholders, a permanent and growing community that collaborates and contributes to building a stronger European Health Union.

Activities will include face-to-face technical training modules on Union public health policies, face-to-face and online workshops, exchange of practices, implementation of projects, an annual conference, and an annual collaborating platform.

The expected result is a growing network of well-trained professionals who have a comprehensive view of the European health agenda, share a solid professional trust base, and the ability to connect swiftly and contribute to resolve outstanding Union and/or national health policy matters. The impact is having a broad and trusted platform for good-faith discussions on better policies to promote health for all people of the Union.

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

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

Indicative budget for this thematic area: EUR 1 400 000

Implementation by: HaDEA

5. DIGITAL (DI)

DI-p-25-66 Administrative and logistical support to the EHDS and other actions in the area of digital health

The Commission is supporting Member States in the digitisation of health and the preparations for the European Health Data Space ('EHDS') through a wide range of actions and fora, including, for example, the eHealth Network, the eHealth Member States Expert Group ('eHMSEG') or the Community of Practice of health data access bodies.

Beyond the current cooperation framework in digital health under Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[147], Regulation (EU) 2025/327 on the European Health Data Space requires the establishment and management of a number of governing bodies, groups, task forces, communities of practice, and fora for which the Commission will provide the secretariat support, including administrative, logistical and technical assistance.

The objective of this action is to provide logistical, administrative, and technical support to the Commission to manage secretariat of the eHealth Network and the eHealth Member State Expert Ggroup (eHMSEG) under the current framework, to assist the governing groups of the EHDS and related fora and in other relevant activities of the Commission for the implementation of the EHDS Regulation or on digital health.

The main activities will aim at:

a) providing administrative, logistical and technical support for the organisation of meetings, in person, hybrid and/or fully online, as needed;
b) assisting the groups in their operational tasks;
c) assisting in the planning and coordination of regular meetings of the various groups, facilitating and managing collaboration platforms and information sharing;
d) maintaining records of participant lists, discussions, decisions, and action points of the meetings and documents;
e) preparing and distributing reports summarising key activities, progress, and upcoming tasks; and
f) providing support for surveys and public consultations, including managing the feedback received, feedback analysis and integration, provide summaries and overviews of the collected feedback.

The expected results and impacts include:

a) streamlined administrative processes and structures tailored for each group;
b) enhanced productivity and effectiveness of the groups;
c) timely and organised scheduling of meetings;
d) well-maintained records of groups, taskforces, and fora activities, discussions, and decisions, aiding in continuity and accountability;
e) improved communication flow within the groups, fostering greater transparency and information exchange; and
f) increased efficiency of management and implementation of surveys and public consultations.

This action complements actions launched under the Digital Europe Programme and Horizon Europe on the EHDS, digital health and health data, such as the xShare project or new actions

147 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0024-20140101.

on supporting patients' access to their health data in the context of healthcare services for citizens across the Union[148], demonstrating the in-service use of the European Electronic Health Record Exchange Format in healthcare settings[149], or to support for Health Data Access Bodies to foster efficient pathways for AI in healthcare[150].

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

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

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA

DI-p-25-67 Compliance checks for MyHealth@EU

MyHealth@EU is the digital services infrastructure developed under Regulation (EU) 2025/327 on the European Health Data Space ('EHDS') for cross-border exchange of health data for provision of healthcare. National Contact Points for eHealth ('NCPeH') providing these services for Member states need to be checked for compliance with MyHealth@EU requirements to become and stay operational.

The objective is to conduct the compliance checks for MyHealth@EU requirements. The specific activities in scope of this action include:

a. the organisation of compliance checks teams, as necessary, and the management of preparatory, follow-up and support activities related to compliance checks;
b. planning and execution of compliance checks;
c. supporting Member States during the compliance checks.

The activities covered by this action are expected to ensure compliance of the participants in MyHealth@EU with the applicable rules and frameworks. The compliance checks will identify findings that may pose risks to confidentiality, integrity or availability of MyHealth@EU services provided. This will increase the trust of participants and other stakeholders in these infrastructures and in the EHDS as a whole.

More broadly, this action will contribute to the implementation of the European Health Data Space in the area of primary uses of health data. This implementation is complemented by actions under the Connecting Europe Facility, the European Regional Development Fund or the Recovery and Resilience Facility aiming at advancing the digitisation of health at national level.

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

Indicative type of contracts/supply: open call for tenders, use of existing or open procedure for a new framework contract

Indicative budget for this thematic area: EUR 2 400 000

148 EU Funding & Tenders Portal.
149 EU Funding & Tenders Portal.
150 Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare - European Commission.

Implementation by: HaDEA

DI-p-25-68 Development, deployment and operations of the central services of the infrastructure on primary uses of health data (MyHealth@EU)

MyHealth@EU, formerly known as eHealth Digital Service Infrastructure or eHDSI, was established under the Cross-Border Healthcare Directive (2011/24/EU)[151] as an EU-level infrastructure for the exchange of health data with voluntary participation of Member States. MyHealth@EU is included in the scope of Regulation (EU) 2025/327 on the European Health Data Space ('EHDS')[152].

This infrastructure provides the possibility for Member States to exchange health data in a secure, efficient and interoperable way. MyHealth@EU services enable 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.

As of late 2024, 15 Member States are connected, and more are in the process of onboarding. Two services are currently operational: ePrescriptions/eDispensations and Patient Summaries. Both services support translation to the language of the country of treatment. 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. The Commission supports this work as policy owner and solution provider for the central services of this infrastructure.

The objective of this action is to support the development, maintenance, and operation of the central services for MyHealth@EU by the Commission. The scope includes all necessary activities to ensure the provision of the central services for MyHealth@EU and their development, including in relation to patient access to health data and the EHDS. The activities to be carried out as part of this action include analysis and design; development, piloting and testing; deployment and operations; and other preparatory or support actions for MyHealth@EU, e.g. studies, technical support, participation of the Solution Provider in the eHealth Member States Expert Group ('eHMSEG') and other fora.

Thanks to this action, the Commission services will be able to continue to support the operations of MyHealth@EU as provided for in the current framework under the eHealth Network and to support Member States in it. This will make sure the infrastructure is ready for its full rollout within the European Health Data Space.

In addition, this action complements actions launched under the Digital Europe Programme on the EHDS, digital health, and health data, such as the actions on supporting patients' access to their health data in the context of healthcare services for citizens across the Union or demonstrating the in-service use of the European Electronic Health Record Exchange Format ('EEHRxF') in healthcare settings.

151 Electronic cross-border health services - European Commission (europa.eu): 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 (europa.eu).

152 European Health Data Space - European Commission (europa.eu).

Moreover, this action complements actions under the Horizon Europe programme funding related on health data interoperability such as XpanDH[153] or the xShare[154] projects in the context of primary uses of health data.

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

Indicative type of contracts/supply: open call for tenders, use of existing or new framework contractor co-delegation with DG DIGIT.

Indicative budget for this thematic area: EUR 2 500 000

Implementation by: DG SANTE

DI-p-25-69 Development, deployment and operations of the central services of the infrastructure on secondary uses of health data (HealthData@EU)

One of the main objectives of the European Health Data Space ('EHDS') is to facilitate the secondary use of health data across Member States. And the establishment of the HealthData@EU cross-border digital infrastructure will be key to facilitating secure, efficient, and cross-border access to health data for the purposes of research, innovation, health policy-making and regulatory activities. This includes the development of new data-driven technologies and solutions, such as artificial intelligence.

The HealthData@EU infrastructure comprises central services managed by the Commission and a network of nodes that includes national contact points and other authorised participants. This dual structure is designed to address the fragmentation of health data access, reduce barriers to cross-border data sharing, and lower the costs associated with accessing quality health data for the secondary use.

The central services of the HealthData@EU infrastructure, to be established and operated by the Commission, will serve as the foundational backbone, facilitating the coordinated functioning of the federated network comprised of Member States' Health Data Access Bodies ('HDABs'). They will offer pivotal functionalities, including the federation of an EU-wide dataset catalogue and a system to manage applications for access to data.

The objective of this action is to support the development, maintenance, and operation of the HealthData@EU central services by the Commission and enhance the infrastructure's capacity to support a seamless exchange of health data among Member States, third countries, and other authorised entities within the EHDS framework. Such exchanges of health data ultimately aim at supporting the reuse of health data across multiple countries for research, innovation (e.g. for artificial intelligence), policy-making and regulatory activities, as provided for in the EHDS Regulation [155]. The action includes all necessary activities to ensure the provision of the central services for HealthData@EU and their development and operation. The activities to be carried out as part of this action include analysis and design; development, piloting and testing; deployment and operations of HealthData@EU central services.

Thanks to this action, the Commission will increase its readiness to provide the services necessary to support the functioning of the HealthData@EU infrastructure. The rollout of this

153 Home - XpanDH Project.
154 Home - xShare.
155 L_202500327EN.000101.fmx.xml

infrastructure will result in a more efficient process for reusing health data, for example in the research and innovation activities related to the development of artificial intelligence. This action will contribute to ensure that the infrastructure is ready for its full rollout within the EHDS.

In addition, it complements actions launched under the Digital Europe Programme (DIGITAL) and Horizon Europe on the European Health Data Space, digital health, and health data. For example, concrete actions linked to the EHDS under those programmes include actions on cancer imaging (DIGITAL), genomic data (DIGITAL) and on data quality and utility (Horizon Europe). This action is undertaken in the EU4Health Programme in line with the budget foreseen under the legislative financial statement accompanying Regulation (EU) 2025/327 on the European Health Data Space.

It supports the deployment of associated services that are critical for enabling strategic health and biotech technologies, such as AI, through secure and cross-border access to health data.

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

Indicative type of contracts/supply: open call for tenders, use of existing or new framework contract or co-delegation with other services.

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: DG SANTE

DI-p-25-70 Actions for EU-level infrastructures and services in the context of the EHDS

Regulation (EU) 2025/327 on the European Health Data Space (‘EHDS’) establishes a health specific ecosystem comprised of rules, common standards and practices, infrastructures, and a governance framework.

MyHealth@EU and HealthData@EU are the main cross-border digital infrastructures included in the EHDS. As of late 2024, MyHealth@EU is already live with 15 countries connected for the cross-border exchange of health data. Beyond those, there are a number of new infrastructures and services that would need to be developed, maintained and operated at the EU level, in particular by the Commission, as part of the EHDS. These include the development and maintenance of the European Electronic Health Record exchange Format (‘EEHRxF’) and other technical specifications for the EHDS, a database for electronic health record (‘EHR’) systems and wellness applications; digital testing environments for EHR systems manufacturers; an interoperable cross-border identification and authentication mechanism for natural persons and health professionals; EU level secure processing environments (for example for the development of artificial intelligence in health); Union data access services or any other infrastructures and services included in the EHDS Regulation.

The objective of this action is to support the development, piloting and operation of such infrastructures and services by the Commission as part of the rollout of the EHDS. This action will build on the outcomes of previous and existing projects, such as the relevant joint actions. The scope includes infrastructures and services to be provided at the Union, in particular by the Commission, in the area of primary and secondary uses within the EHDS beyond MyHealth@EU and HealthData@EU. The activities to be carried out as part of this action may include, based on the needs for the rollout of the EHDS:

a. elicitation of requirements and specifications for the infrastructures and services to be provided and operated by the Commission;
b. analysis and design of the infrastructures and services;
c. their development, piloting and testing;
d. their deployment, maintenance and operations;
e. provision of reference implementations; and other preparatory or support actions and building capacity at the Commission (e.g. studies).

This action will contribute to the readiness of the Commission to support the rollout of the EHDS Regulation. As a result of these activities, the Commission will be able to take the necessary steps to support Member States and stakeholders in the implementation of the EHDS.

Moreover, this action complements actions launched under the Digital Europe Programme and Horizon Europe on the EHDS, digital health and health data. Moreover, the Horizon Europe programme is also funding related to health data interoperability such as XpanDH[156] or the xShare[157] project in the context of primary uses of health data. This action is undertaken in the EU4Health Programme given that the central services for the EHDS infrastructures are implemented directly by DG SANTE, on behalf of the Commission. It also supports the Europe's Beating Cancer Plan by rolling out the horizontal infrastructures for the implementation of the EHDS, which is a fundamental initiative to support cancer research and access to health data by cancer patients.

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 (a) and (f), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: open call for tenders, use of existing or new framework contract, administrative agreements or co-delegation with relevant services.

Indicative budget for this thematic area: EUR 4 000 000

Implementation by: HaDEA/DG SANTE

156 Home - XpanDH Project.
157 Home - xShare.

6. RECURRENT, HORIZONTAL, IT AND COMMUNICATION ACTIVITIES

The actions have as objectives the organisation of events and meetings through covering expert expenses, including special indemnities, in particular in relation to participation in steering groups and expert panels, in the field of health, the logistical support to meetings of expert groups and similar entities as well as of scientific committees (e.g., Scientific Committee on Consumer Safety, Scientific Committee on Health, Environmental and Emerging risks, etc.) in the field of risk assessment and research, the support to the Health Policy Platform to build up good collaboration and communication channels with its health stakeholders and health networks, the support in studies, analysis, impact assessments and evaluations of health-related legislation. These activities will also cover the participation of Union delegates to the International Medical Device Regulatory Forum (IMDRF), as well as the expenses of experts participating in Commission controls and audits in the pharmaceutical field.

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

In line with the Commission's ambition to build a European Health Union for people and the Commission's One Health approach, communication in 2025 will focus on key political priorities.

These actions also cover the experts' evaluation for proposals and tenders received by HaDEA and monitoring of certain projects, studies and experts and technical support for the implementation of Regulation (EU) 2017/745[158] and Regulation (EU) 2017/746[159], and other Union legislation on health and policies related.

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

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

These actions also cover expert legal support for the assessment of the regulatory alignment with Union law in the context of enlargement. This assessment will help candidate countries to proceed with the adoption of the national legislation aiming at the full alignment with the Union acquis in the field of public health. The assessment of the compatibility is also essential for the Commission services to provide adequate recommendations for the next steps.

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158 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).

159 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).

A new Better Regulation framework contract needs to be launched in 2025 to be used under EU4Health.

These actions implement the EU4Health Programme's overall objective to improve human health throughout the Union and to ensure a high level of protection of human health in all Union policies and activities and all general objectives referred to in 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.

The expected results are:

a) **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
b) **for IT:** provision of corporate technical services;
c) **for translations:** provision of translation services including for the 5th edition of the European Code against cancer and others as needed;
d) **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 in particular for priority actions to be undertaken in accordance with the political guidelines and the mission letters of the 2024-2029 Commission;
e) **for the assessment of national transposing measures in the context of the enlargement conformity:** the assessment is intended to support the final assessment of the legislative alignment of the candidate countries and potential candidate for which the Commission is responsible. It implies checking the alignment of national measures with the relevant pieces of Union legislation, aiming at the full alignment with the Union acquis in the field of public health. The assessment of the compatibility is also essential for the Commission services to provide adequate recommendations for the next steps;
f) **for Better Regulation:** a new framework contract will be established;
g) **for implementation of the health legislative framework**: reimbursement of the expenses incurred by experts participating in Commission controls and audits in the pharmaceutical field, including in relation to GMP and/or GDP, as well as the participation of Union delegates to the International Medical Device Regulatory Forum ('IMDRF'), the Medical Device Single Audit Programme ('MDSAP') and other activities related to outreach at international level and the development of standards in the field of medical devices.

Within this thematic area, the Commission plans to launch open procedures for a framework contract for services related to the better regulation.

Indicative type of contracts/supply: service contract based on exiting framework contract, open procedures or competitive procedures with negotiation or competitive dialogue procedure, administrative arrangements, co-delegation with DG COMM, DG DIGIT and DG DGT.

Indicative budget for this thematic area: EUR 10 465 340

Implementation by: DG SANTE / HaDEA / HERA

C. OTHER ACTIONS AND EXPENDITURE

In 2025, the Commission intends to launch the following actions which contribute to one or several strands.

DP-o-25-71 Subscription of access to the Euromonitor Online Database

The legislative framework for tobacco control is currently under evaluation, including the Tobacco Products Directive 2014/40/EU[160], Tobacco Advertising Directive 2003/33/EC[161] and related tobacco control policies across the Union. This action will provide DG SANTE access through an online integrated database to market research data relating to the consumption of tobacco and related products as well as information on the tobacco and related industries.

Information, data and intelligence obtained through access to the Euromonitor online databases may serve as complementary input to the preparation of the Impact Assessment for the evaluation.

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.

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

Indicative type of contracts/supply: Subscription fee

Indicative budget for this thematic area: EUR 50 000

Implementation by: DG SANTE

DP-o-25-72 Scientific Committees, functioning of experts' groups, meetings and technical assistance

The Scientific Committees on Consumer Safety ('SCCS') and on Health, Environmental and Emerging Risks ('SCHEER') provide the Commission with advice on diverse scientific issues.

When preparing policy and proposals related to areas of safety of cosmetic ingredients, health and the environment, the Commission relies on these two independent Scientific Committees to provide sound scientific advice and draw its attention to new and emerging problems.

The opinions of the scientific committees inform and help in shaping Union policies and legislation, leading to evidence-based decision-making and effective risk management ensuring health and safety of Union citizens in key areas such as chemicals, consumer products and environmental factors. Transparency and scientific rigour in their assessments build public trust in Union institutions and their ability to manage health and environmental risks.

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160 Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC; OJ L 127, 29.4.2014, p. 1–38.

161 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. 16–19.

Committees have been set up by Commission Decision 2024/1514/EC[162].

Through this action the Commission will receive:

- scientific opinions (mandated by the Commission services and published, web-activities, monthly expert group meetings, plenary meetings, technical support);
- assistance to the Communication team (e-newsletter) and Health Policy Platform meetings;
- networks of experts (IT tools, web page, public consultations, public hearings, calls for experts, working meetings, thematic workshops).

It is expected to:

- develop the scientific evidence base 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.
- contribute to faster and informed policy-decision making.

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: expert fees.

Indicative budget for this thematic area: EUR 740 000

Implementation by: DG SANTE

HS-o-25-73 Methodologies for assessment of safety and performance or market surveillance of silicone-containing medical devices

The implementation of Regulation (EU) 2017/745[163] and Regulation (EU) 2017/746[164] is a priority for the Commission, as highlighted in the mission letter from Commission President von der Leyen to Commissioner for Health and Animal Welfare, the Council Conclusions on the Future of the European Health Union of June 2024 and several debates in the EPSCO Council, the last one in December 2024.

By improving testing methodologies and procedures, the Commission can better protect the health and well-being of patients who rely on these medical devices. With a focus on ensuring the safety and performance of devices primarily used in women, it is crucial to develop better methodologies for testing. This action contributes to the general priority of gender equality in the Union.

This includes the standardisation of testing procedures, which contributes to greater transparency, consistency, and confidence in the safety and performance of medical devices. The development of better testing methodologies for medical devices in scope of the action also

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162 Commission Decision (EU) 2024/1514 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment (OJ L, 2024/1514, 31.5.2024).

163 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).

164 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).

ties in with the Commission's policy on combating cancer, particularly in the context of Europe's Beating Cancer Plan. Breast and cervix cancer are significant concerns for women's health, and ensuring the safety and performance of medical devices used in women is crucial. By prioritising the implementation of the new regulations and improving testing methodologies, the Commission can contribute to the overall goal of managing the burden of cancer and improving the life quality for patients with these specific types of cancer.

The actions in this thematic section aim to provide scientific support for the implementation of the Regulation on medical devices, with an overall objective of reinforcing safety requirements for all manufacturers placing their products on the Union market. This work will build and expand ongoing work related to silicone breast implants and anaplastic large cell lymphoma – BIA-ALCL, a type of blood cancer. The goal is to equip manufacturers, notified bodies and regulators with the necessary means to generate the pre-clinical and clinical evidence and assess the safety of the breast implants placed on the Union market and, as a consequence, to improve women's health. Specifically, this work will continue the development and expand the use of methods for the characterisation of breast implants to other silicone implantable devices, including long-and short-term use devices such as intra-uterine or intra-vaginal devices and various catheters. This action will build on the results of an existing administrative arrangement between SANTE and JRC (2021 EU4Health work programme action HS-p-19.1) on the surface and biological characterisation of breast implants. The experience, know-how and instrumentation from this administrative arrangement will be used to develop methods being established and so as they are adequate for other types of devices, including by testing actual products. Furthermore, this work will explore practical applications based on the scoping study on expert laboratories under the second administrative arrangement between SANTE and JRC (HS-o-24-102).

The developed methodologies will provide the Member States with the tools needed to enhance their regulatory oversight for national assessments and market surveillance. Medical devices manufacturers will also benefit from improved methodologies for conducting pre-market studies, ensuring the safety and performance of their products. The establishment of robust pre-clinical data will thus support evidence-based market access and regulatory measures.

The planned actions also include contribution to ISO standardisation activities, laying the groundwork for further standardisation efforts in other areas, similar to the work done to revise ISO 14607 on breast implants currently undertaken under an administrative arrangement funded by the 2021 EU4Health work programme action HS-p-19.1. Overall, these actions will lead to improved methodologies for national assessments, market surveillance, and pre-market studies, ultimately enhancing the safety and effectiveness of medical devices on the market world-wide.

This action implements the EU4Health Programme’s general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases by supporting health promotion and disease prevention (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (c), and (i), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 400 000

Implementation by: DG SANTE

Membership fees to International Organisations and regulatory bodies

DP-o-25-74 Annual contribution to the European Observatory on Health Systems and Policies Partnership

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

This action implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases by supporting health promotion and disease prevention (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (c), of Regulation (EU) 2021/522.

Indicative budget for this thematic area: EUR 700 000

Implementation by: DG SANTE

HS-o-25-75 Annual membership fee to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[165] and participation of experts from Member States in ICH meetings

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ('ICH') is the main multilateral international harmonisation venue dealing with "standard-setting" in the field of medicinal products for human use. ICH brings together the regulatory authorities and pharmaceutical industry to achieve greater harmonisation worldwide to ensure that safe, effective and high-quality medicines are developed, registered and maintained in the most resource efficient manner whilst meeting high standards. The Commission is a Founding Regulatory Member of the ICH (which was established in 1990 at the initiative of the Commission).

ICH's main objectives are to improve efficiency of new development and registration process for medicinal products for human use as well as to promote public health, prevent duplication of clinical trials in humans and minimise the use of animal testing without compromising safety and effectiveness. These objectives are accomplished through the development and implementation of harmonised ICH Guidelines on quality, safety and efficacy of pharmaceuticals, which are referred to as international standards.

In line with the Pharmaceutical Strategy for Europe to ensure a strong voice globally in international pharmaceutical fora, promote regulatory convergence and harmonisation, active engagement in ICH, enables harmonisation of international "standard-setting" in the field of medicinal products for human use, promotion of Union policy interests and engagement in a multilateral dialogue on technical and scientific matters. Development of the guidelines for submission of applications for authorisations of medicinal products and for the maintenance of those authorisations is an essential aspect of the implementation of the legislation on medicinal products. The ICH guidelines thus complement the Union legislation and policy in the field of pharmaceuticals and contribute to the protection of public health.

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

This annually recurring action covers the annual membership fee to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and the participation of experts from Member States in ICH meetings.

The action implements the EU4Health Programme's general objective of improving the availability, accessibility, and affordability of medicinal products in the Union and supporting innovation (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 budget for this thematic area: EUR 669 000

Implementation by: DG SANTE

HS-o-25-76 Annual contribution to the International Pharmaceutical Regulators Programme[166] (IPRP)

The International Pharmaceutical Regulators Programme ('IPRP') was created in 2018 (replacing the previous Regulators' forum) to promote exchange of information, collaboration and possible convergence of regulatory approaches for pharmaceutical medicinal products for human use. It is composed solely of regulatory authorities and its physical meetings are convened in conjunction with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for human use ('ICH') biannual meetings.

In line with the Pharmaceutical Strategy for Europe to ensure a strong voice globally in international pharmaceutical fora, engagement in IPRP enables promoting regulatory convergence and exchanging of information and best practices with our international partners on issues of mutual interest in the field of medical products for human use, promotion of Union policy interests and engagement in a multilateral dialogue on technical and scientific matters.

This annually recurring action covers the annual contribution to the International Pharmaceutical Regulators Programme, of which the Commission is a member, and implements the EU4Health Programme's general objective of improving the availability, accessibility, and affordability of medicinal products in the Union and supporting innovation (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 budget for this thematic area: EUR 31 000

Implementation by: DG SANTE

HS-o-25-77 Joint assessment of Notified Bodies and associated training for experts

This action is to reimburse expenses incurred by national experts participating in:

- joint assessments in the medical devices field, which are carried out in the context of the designation of conformity assessment bodies (Article 39 of Regulation (EU)

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

2017/745[167] and Article 35 of Regulation (EU) 2017/746[168]), the re-assessment of notified bodies (Article 44 of Regulation (EU) 2017/745 and Article 40 of Regulation (EU) 2017/746), or the extension of notified bodies' scope of designation (Article 46 of Regulation (EU) 2017/745 and Article 42 of Regulation (EU) 2017/746);

- training related to the above-mentioned tasks.

It is to ensure that the Notified Bodies are appropriately resourced and adequately performing.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, 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: Reimbursement of experts

Indicative budget for this thematic area: EUR 100 000

Implementation by: DG SANTE

HS-o-25-78 Support to the peer review between authorities responsible for notified bodies

Availability of safe and performant medical devices and *in vitro* diagnostics is essential in the diagnosis and treatment of European patients. In 2017, Regulation (EU) 2017/745[169] and Regulation (EU) 2017/746[170] were adopted to safeguard patient safety whilst supporting innovation in the sector.

Under Regulation (EU) 2017/745 and Regulation (EU) 2017/746, actors of the medical devices/*in vitro* diagnostics field have a variety of actions to perform. For instance, national competent authorities designate notified bodies to perform third-party conformity assessment activities. As part of their role to designate notified bodies, the national authorities responsible for notified bodies must participate in peer-review activities to exchange experience and coordination of administrative practice between authorities.

This action supports the Commission and national competent authorities in complying with the legal obligations set out in Article 35 and Article 48 of Regulation (EU) 2017/745 and Article 31 and Article 44 of Regulation (EU) 2017/746.

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

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167 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).

168 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).

169 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).

170 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).

This action aims to support national competent authorities in the peer review activities and exchanging of experience between competent authorities responsible for notified bodies.

The activities are expected to result in a more harmonised implementation of activities performed by authorities responsible for notified bodies by means of the peer review process laid out in Regulation (EU) 2017/745 and Regulation (EU) 2017/746 to ensure a predictable and reliable regulatory framework that supports patient safety and innovation in the medical device and *in vitro* diagnostics sector in the Union.

Indicative type of contracts/supply: Reimbursement of experts

Indicative budget for this thematic area: EUR 40 000

Implementation by: DG SANTE

D. ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT

In 2025, the Commission intends to undertake actions through indirect management mode, whereby the Commission delegates budget implementation tasks to third entities to achieve a set of Union objectives relying on their rules, systems, and procedures. Indirect management is the appropriate management mode for entrusting Union funds to international organisations that have undergone an ex-ante assessment of their rules, systems, and procedures - the so-called 'pillar assessment' - in accordance with Article 157(4) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council (the 'Financial Regulation').

CP-CA-25-79 Supporting the development of medical countermeasures against antimicrobial resistance to strengthen global preparedness and response (HERA)

POLICY CONTEXT

Antimicrobial resistance ('AMR') is a major threat to health, which was associated to more than 35 000 deaths annually in the Union[171] and against which efficient medical countermeasures, including vaccines, diagnostics, antimicrobials and alternatives are lacking. HERA has thus included AMR in its list of priority threats. The antimicrobial market faces structural issues that discourage private investment, such as development costs, low return on investment, and stewardship measures (which limit sales to prevent resistance) reduce the profitability of new antimicrobials. Overcoming these barriers and fostering development is essential to combatting AMR effectively.

A sustainable AMR response requires uninterrupted funding throughout the development process, from early-stage research to market availability. Disruptions in funding could result in the loss of promising candidates or delay life-saving treatments.

Since 2022, HERA has partnered with the WHO to support the innovation in the field of AMR including through the Global Antibiotic Research & Development Partnership ('GARDP'), which addresses later-stage clinical development and access to new antimicrobials ('Action CP-g-06.7 Strengthening preparedness and response to cross-border health threats at global level' of the 2021 EU4Health work programme). This partnership has shown a need for a more holistic approach to innovation to ensure a comprehensive and sustainable pipeline. This is why HERA intends to extend support to initiatives that cover not only late-stage research but also ensure that promising products reach the clinical phase so that the Union can ensure access to the necessary products to tackle AMR.

This aligns with the recommendations of the EC-commissioned study "*Bringing AMR medical countermeasures to the market*"[172]. The study emphasised the importance of international coordination and avoiding duplication of efforts. It also highlighted the value of existing mechanisms for push funding and Union investment on them. These mechanisms include not only GARDP, but also the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator ('CARB-X'), which focuses on accelerating preclinical research and advancing potential medical countermeasures, thereby addressing critical gaps in the fight against AMR.

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171 See ECDC press release (November 2022): 35 000 annual deaths from antimicrobial resistance in the EU/EEA.

172 Study on bringing AMR medical countermeasures to the market - Publications Office of the EU.

Furthermore, the Political Declaration of the High-level Meeting on Antimicrobial Resistance[173], adopted on 9 September 2024, recognised the significance of public-private partnerships in the development and accessibility of antimicrobials, vaccines, diagnostics, and alternatives. The declaration also recognised the role of such partnerships in ensuring supply chain sustainability and specifically acknowledged the contributions of CARB-X and GARDP in tackling AMR challenges.

In order to tackle the market failure in the area of AMR, strengthen access of AMR MCMs in the Union and ensure an adequate coordination with the abovementioned international actors, HERA has identified Kreditanstalt für Wiederaufbau ('KfW') as the most suitable beneficiary for this action, in accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522. The KfW is perfectly positioned to implement this action due to its extensive experience in managing international funding programmes and fostering public-private partnerships to accelerate access of MCMs in the Union and globally, especially in niche areas where there is a need to de-risk investments to ensure innovation and availability of products.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to support ongoing and effective global initiatives to ensure innovation and access to AMR MCM especially those led by CARB-X and GARDP. KfW will coordinate the support to innovative products in this area in order to ensure synergies in the activities to be undertaken and a holistic approach in innovation investments, in a way that promising products can reach the clinical phase and then been pulled as much as possible in the development pipeline, in synergy with Horizon Europe-funded projects.

Specifically, the action aims to provide push funding for the development of new antimicrobials, ensuring their sustainable accessibility while promoting responsible use and affordability. By doing so, this action will enhance health protection within the Union, significantly strengthening pandemic prevention, preparedness, and response in the context of AMR.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

a. Enhanced health preparedness and resilience reducing the burden of AMR-related morbidity and mortality;
b. an increased development and innovation of AMR medical countermeasures addressing market failures in the field; and
c. increased availability of AMR medical countermeasures.

[173] Political Declaration of the High-level Meeting on Antimicrobial Resistance 2024.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-25-79	Q3-Q4/2025	EUR 30 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Indirect management	HERA	KfW

CP-CO-25-80 Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the Invest EU Programme[174] (HERA)

POLICY CONTEXT

The best way to master future health crises is to anticipate and prepare before they materialise. The Communication "*Drawing the early lessons of the COVID-19 pandemic*" [175] 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. There is a need to combine public and private efforts to incentivise breakthrough research and innovation and strong manufacturing basis in the health ecosystem, making it more resilient.

This action will be conducted in accordance with Article 10 of Regulation (EU) 2021/522.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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

OBJECTIVES, SCOPE AND ACTIVITIES

With this action, HERA will contribute to the Thematic Innovation - Research, Innovation and Digitalisation Window ('RIDW') financial product (more specifically, in the policy area '1.1 Health innovation investment') implemented by the European Investment Bank ('EIB') under the Invest EU programme. HERA will also contribute to the EIB financial products under the SME Policy Window to ensure access and availability of finance primarily for SMEs, as well as for small mid-cap companies and to the InvestEU Advisory Board.

The aim of the action is to support investments into companies developing R&D solutions or increasing sustainable manufacturing of medical countermeasures for pandemic preparedness,

174 This blending operation is referred to as "HERA INVEST".

175 Communication on the early lessons from the COVID-19 pandemic (europa.eu).

in particular into vaccines and other preventive interventions, therapeutics (including critical medicines), and diagnostics, as mentioned in the guaranteed agreement between the EIB and the Commission. The funds will be managed by DG GROW via cross sub-delegation. The implementing entity is the EIB. HERA will cooperate with EIB for the implementation of the action.

The aim of the action is to support investments, through venture loans and advisory services, 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 using public funds to incentivise private investment, and contributing to the R&D pipeline of medical countermeasures against serious cross-border health threats.

At present, there is no European private or public/private financing facility specialising in providing financial support to the development or manufacturing of a wide range of medical countermeasures dealing with AMR, CBRN and pathogens with pandemic potential. International organisations such as CEPI[176] or the novel WHO/World Bank financial intermediary fund focus or will focus either on the development of only one class of medical countermeasures, or do not sufficiently fund end-to-end (early research to market) development of medical countermeasures. Moreover, their focus is international. Their investments do not always guarantee the Union development and availability of medical countermeasures in times of crises and may not meet the objectives of European strategic autonomy and resilience. HERA has a unique opportunity to alleviate this market failure and provide European autonomy in the development of lifesaving medical countermeasures.

Thanks to this action a number of priority health threats and medical countermeasures based on HERA's prioritisation activities will be funded, in synergy with the actions funded under Horizon Europe. Therefore, in order to ensure a better understanding of the extent to which market failures of suboptimal investments in medical countermeasures can be mitigated, investments will focus on projects targeting the development of preventative, treatment or diagnostics medical countermeasures for a specific group of pathogens. In addition, the investment should be made into early to late-stage SME life sciences companies developing a platform (i.e., tackling also other targets that are commercially attractive). This will allow for higher chances of repayment and economic success of the initiative.

EXPECTED RESULTS AND IMPACT

This action can effectively incentivise private investment by leveraging public funds, therefore contributing to the Thematic Innovation financial product, allowing the EIB to increase their volume of venture loans into specific areas as described above and bringing in other investors. A broad investment portfolio further minimises risks, especially if investments are made into platform technologies. Using a top up of a thematic financial product provides for control and ownership via the Invest EU eligibility checklist procedure, as well as inclusion of third parties.

The action aims at attracting third party investors through co-investment, for example from Member States, international donors and private investors. The action promotes innovation and

176 CEPI | New Vaccines For A Safer World.

development of new medical countermeasures and will create positive spill overs for international partners.

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(a).

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CP-CO-25-80	Q3-Q4/2025	EUR 20 000 000
Procedure type	**Implemented by**	**Implementing Entity**
Indirect management	Co-delegation type II to DG GROW	EIB

CP-CA-25-81 Supporting the Development of Dengue Medical Countermeasures, Anticipating Growing Needs in the Union due to Climate Change (HERA)

POLICY CONTEXT

Dengue fever, a mosquito-borne viral disease, poses a growing threat to global and European public health due to the expanding range of its primary vectors, Aedes aegypti and Aedes albopictus, driven by climate change. The European Centre for Disease Prevention and Control ('ECDC') has reported an increase in local transmission of dengue within the Union, with outbreaks becoming more frequent and widespread. As climate change becomes increasingly prominent it creates favourable conditions for mosquito proliferation, making dengue a growing health concern in the Union.

Currently, no specific antiviral treatments exist to mitigate the severity of dengue infection or reduce its transmission. Existing interventions focus on vector control and supportive care, which, while essential, do not fully address the growing burden of the disease. The World Health Organization ('WHO') has identified the development of dengue-specific treatments as a critical global health priority, highlighting their potential to complement existing strategies and improve public health outcomes.

The market for dengue antivirals faces similar challenges to those observed in other health related challenges, like antimicrobial resistance, such as high development costs, low profitability, and limited investment from the private sector. These structural barriers have delayed the development of life-saving therapeutics, making public-private partnerships and sustained funding essential to advance R&D in this area.

This action will enable the Union to strengthen its crisis preparedness and response capacities for vector-borne diseases. By supporting the development of critical medical countermeasures, HERA can help ensure that future dengue fever outbreaks are addressed with effective, accessible, and affordable solutions.

This action will be implemented by the Agence Française de Développement ('AFD'), which has extensive experience in this field, managing health programs, as well as the necessary convening power and ability to coordinate international health programs and fostering collaboration among diverse stakeholders. This action will be implemented in cooperation with Drugs for Neglected Diseases initiative ('DNDi') a non-profit global initiative that has launched efforts to accelerate the development of dengue-specific antiviral treatments. DNDi's approach aligns with HERA's commitment to fostering innovative medical countermeasures to address emerging health threats, including those exacerbated by climate change. This action will therefore focus in developing treatments for diseases that lack sufficient commercial investment. AFD's global mandate will ensure the alignment of this initiative with international health priorities, facilitating efficient implementation of this project and maximizing its impact.

In accordance with Articles 7(1) and 13(1), point (b), f Regulation (EU) 2021/522, AFD is an eligible legal entity to implement this action. AFD is well-positioned to coordinate this action due to its extensive experience in managing international funding programmes, including in the areas of health and R&D, and fostering public-private partnerships. Additionally, AFD is a Pillar-assessed institution that has partnered with DNDi since 2006, sharing a strong commitment to addressing unmet treatment needs for neglected diseases.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims, among others, to support AFD coordinating R&D activities for at least two candidate medicinal products for dengue fever's treatment, including through clinical trials' related activities in collaboration with DNDi.

Specifically, this action will provide support to ensure that promising drug candidates advance through clinical evaluation, addressing current treatment gaps in late-stage development pipeline for dengue therapeutics. It is expected that the drugs selected have demonstrated strong performance in earlier stages of development, with a particular focus on safety, efficacy, and scalability.

Activities under this action include:

- design and implementation of advanced clinical trials for (at least two) dengue's promising medicinal product(s), e.g. through traditional clinical trials (such as randomized controlled trials) or platform trials;
- ensuring adherence to the highest scientific and ethical standards, especially considering that some activities will be most likely run in low- and middle-income countries;
- engage, where applicable, with Union's regulatory authorities to ensure that successfully developed products are available in the Union;
- support pipeline analysis of relevant dengue MCMs candidates; and

- promote collaboration among research institutions, public health authorities, and private sector stakeholders.

By doing so, this action will contribute to the availability of effective dengue treatments, enhancing Union's capacity to respond to the growing health threat posed by this disease.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

a. Support for the development of (at least two) medicinal product(s) for treatment of dengue;
b. Decrease of the overall (including future) dengue's risk of transmission and of severe disease in the Union;
c. Improvement of public health outcomes and a reduction of the burden of dengue on healthcare systems, by reducing hospitalisations and lowering mortality rates; and
d. Improvement of health preparedness in the field of vector-borne diseases, by increasing the number of available MCMs in the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-25-81	Q3-Q4/2025	EUR 20 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Indirect management	HERA	AFD

CP-CA-25-82 Support to pandemic and epidemic intelligence (HERA)

POLICY CONTEXT

HERA aims to support digital capacities that can speed-up the detection and improve the characterisation of emerging pathogens, as necessary to swiftly develop, update and deploy the adequate medical countermeasures ('MCM'). Several tools developed by the WHO Hub for epidemic and pandemic intelligence contribute to this objective, in particular the Epidemic Intelligence from Open Sources ('EIOS')[177] initiative, which gathers open-source intelligence for public health decision-making, and the WHO-Collaboratory[178], which is a collaborative space for modellers to share data tools and models. Both initiatives deliver outputs that inform HERA's decision making on MCM preparedness and response and that can as well benefit other Union services and agencies. HERA is notably working closely with the ECDC, since both entities are members of the EIOS coordination group.

HERA established a structured collaboration with the WHO Hub for Pandemic and Epidemic Intelligence through a Memorandum of Understanding signed in December 2022. This

177 https://www.who.int/initiatives/eios.
178 WHO Collaboratory.

Memorandum recognises their commitment to contribute to strengthening the global health security architecture by fostering Union and international engagement in the context of global health threats and availability of and access to medical countermeasures for preparedness, prevention, detection of, and response and recovery to public health emergencies.

This action supports the renewal of the agreement between HERA and WHO Hub regarding initiatives for improving pandemic and epidemic intelligence.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, WHO is the eligible legal entity to implement this action. 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.

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 (a), (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will support the implementation of the MoU between HERA and WHO Hub and supports the WHO-Hub activities on pandemic and epidemic intelligence relevant to medical countermeasures. In particular, this action can support activities to further support tools and projects supported by previous HERA-WHO-Hubs contribution agreements, for example the EIOS or the WHO-Collaboratory, a digital environment where the epidemic intelligence community can convene and address challenges in data access, analyses, visualisation, and communication for better decision making.

EXPECTED RESULTS AND IMPACT

This action supports better digital and collaborative tools for early detection and analysis of emerging threats, in order to improve MCM preparedness and response to cross-border health threats. It is a renewal of the previous agreement with a revised programme, to support WHO-Hub initiatives for improving pandemic and epidemic intelligence. The new agreement might provide further support to the projects and tools supported so far, including EIOS or the WHO-Collaboratory.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-25-82	Q3-Q4/2025	EUR 4 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**

Indirect management	HERA	WHO

CP-CA-25-83 Support of the independent antimicrobial resistance evidence panel for global policy and response (HERA)

POLICY CONTEXT

Antimicrobial resistance (‘AMR’) poses a growing threat to global health. On 26 September 2024, during the United Nations (‘UN’) General Assembly (UNGA) High-Level Meeting on Antimicrobial Resistance, global leaders adopted a Political Declaration on AMR[179]. This declaration underscores the urgent need to address the escalating threat of AMR to human, animal, and environmental health. Among its key commitments is the creation of an independent panel for AMR evidence in 2025.

This panel will generate and provide scientific, multisectoral evidence to support policy decisions and enhance global AMR responses. The declaration invites the UN Quadripartite, comprising the Food and Agriculture Organization (‘FAO’), the United Nations Environment Programme (‘UNEP’), the World Health Organization (‘WHO’), and the World Organisation for Animal Health (‘WOAH’), to set up the panel. This collaborative effort aims to provide a unified, evidence-based approach to addressing the AMR crisis.

The Commission welcomed the Political Declaration as a strong signal of the global consensus on the necessity to address this serious global health threat. The Commission announced its support to fund the independent panel for evidence-based action against AMR [180].

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, the UN quadripartite is the eligible legal entity to implement this action. The UN quadripartite has joined forces to underscore the threat AMR presents to humans, animals, plants, ecosystems and livelihoods. It has launched a platform to tackle antimicrobial resistance threat to human and animal health and ecosystems and, as announced in the UNGA it will host the independent panel.

This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures, with a focus on AMR. It implements the EU4Health Programme’s general objective of improving the availability, accessibility, and affordability of crisis-relevant products (Article 3, point (c), of Regulation (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 the UN Quadripartite in setting up an independent panel for evidence-based action against AMR. Financially supporting this independent panel is crucial to ensure objective, interdisciplinary analysis that informs policy and innovation. It reflects a proactive approach for safeguarding human, animal and environmental health against the escalating risks posed by AMR.

The panel should facilitate the generation and use of multisectoral, scientific evidence to support Member States in efforts to tackle antimicrobial resistance, making use of existing

179 FINAL-Text-AMR-to-PGA.pdf.
180 International declaration on the fight against AMR.

resources and avoiding duplication of on-going efforts. There should be an open and transparent consultation with all Member States on its composition, mandate, scope, and deliverables.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

a. Enhanced evidence for policy and decision-making to tackle AMR challenges;
b. Promotion of innovation in research and development of medical countermeasures to tackle AMR; and
c. Strengthened global collaboration providing informed sustainable global actions against AMR.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-25-83	Q3-Q4/2025	EUR 2 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Indirect management	HERA	UN Quadripartite (FAO, UNEP, WHO, or WHOAH)

CP-CA-25-84 Strengthening global antimicrobial resistance response: supporting WHO's AMR efforts in fostering innovation in R&D and ensuring access to essential medicines (HERA)

POLICY CONTEXT

Antimicrobial resistance ('AMR') is a major threat to health, which was associated to more than 35 000 deaths annually in the Union[181] and against which efficient medical countermeasures, including antimicrobials, are lacking. HERA has thus included AMR in its list of priority threats.

HERA partnered with WHO in 2022 for the development of new medical countermeasures against AMR. This agreement was signed under the 2021 EU4Health work programme ('Action on CP-g-06.7 Strengthening preparedness and response to cross-border health threats at global level') and supported activities aiming at informing R&D of new MCM, including the publication and implementation of priority bacterial and fungal pathogen lists, as well as of the pipeline analyses for antibacterials and antifungals. It also funded the SECURE initiative[182] for accelerating access to newly registered and generic essential antibiotics and supporting countries in addressing drug-resistant bacterial infections.

WHO also carries out initiatives that can accelerate the development of other AMR MCMs than traditional antibacterials and antifungals, including initiatives on AMR diagnostics, non-

[181] See ECDC press release (November 2022): "35 000 annual deaths from antimicrobial resistance in the EU/EEA

[182] See: gardp.org/secure/.

traditional therapeutics[183] or AMR vaccines[184]. In accordance with Articles 7(1), and 13(1) point (b), of Regulation (EU) 2021/522, WHO is the eligible legal entity to implement this action. The award of the action to WHO is duly justified since WHO is well placed to provide strategic direction to enhance global response to the rising threat of AMR by prioritising and coordinating the global research and development ('R&D') efforts to address the ongoing void in AMR medical countermeasures.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action will support ongoing and effective global initiatives coordinated by the WHO that can bring an added value to health protection in the Union by significantly improving pandemic prevention, preparedness, and response in the area of AMR.

In particular, this action aims to support the WHO activities to guide R&D efforts for antibacterials, antifungals, as well as for non-traditional therapeutics, diagnostics and vaccines against AMR, as well as the WHO and Global Antibiotic Research & Development Partnership ('GARDP') in its common initiative SECURE to ensure sustainable access to these treatments while promoting responsible use and affordability.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

- An increased development of AMR medical countermeasures;
- Innovation in AMR medical countermeasures development;
- And increased availability of AMR medical countermeasures.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-25-84	Q3-Q4/2025	EUR 3 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Indirect management	HERA	WHO

183 https://www.who.int/europe/news-room/events/item/2024/04/18/default-calendar/webinar---towards-building-the-evidence-for-broader-use-of-bacteriophages-from-an-amr-one-health-perspective.

184 https://www.who.int/news/item/12-07-2022-urgent-call-for-better-use-of-existing-vaccines-and-development-of-new-vaccines-to-tackle-amr.

CP-CO-25-85 Support the G7 Surge Financing Initiative for MCMs and the Accessibility and Availability of MCMs through Innovative Funding Mechanisms (HERA)

POLICY CONTEXT

In the aftermath of COVID-19, the U.S. International Development Finance Corporation ('DFC'), the G7 Development Finance Institutions ('DFIs'), the European Investment Bank ('EIB'), and the International Finance Corporation ('IFC'), started exploring ways to work together to expand procurement, production, and distribution of medical countermeasures ('MCMs'), both in preparation for health emergencies and during pandemic outbreaks. This was formalised as the "*G7 Surge Financing Initiative for MCMs*" with a Memorandum of Understanding ('MoU'), signed by all parties at the recent 2024 United Nations' General Assembly ('UNGA'). The MoU outlines the intention for the parties to collaborate in providing coordinated surge financing through the establishment of seven financing initiatives, of which two are being prioritised for development:

- **Liquidity Facility for Donor Financing** – to provide immediate liquidity to place orders for MCMs based on donor commitments.
- **Working Capital Facility for LMIC Manufacturers** – to support manufacturers in low- and middle-income countries ('LMIC') with working capital to scale up production during and in preparation for health emergencies.

The initiative is governed by a Secretariat, which is hosted on a rotation basis by one of the lead DFIs. DFC has been appointed as the MoU lead with responsibility for outlining the structure and priorities, while EIB is the Platform Framework lead with responsibility for communication plans and coordination protocols. There are also lead DFIs for each of the Working Groups, with EIB leading the "*Donor Financing Liquidity Facility*" and IFC leading the "*Working Capital Financing Facility*".

This action will therefore support the EIB and remaining partners to fund the Secretariat's and its activities, ensuring good overall coordination and the necessary support for the development of new tools for counteracting cross-border health threats, as well as platforming new funding schemes for delivering MCMs in LMICs.

This action will support the Union's preparedness, by increasing its visibility, awareness, and deal sourcing opportunities. Likely, it will also support ongoing work in developing and (in the future) implement the Union strategy to support MCMs against public health threats.

Where appropriate, this action will be conducted in accordance with Article 10 of Regulation (EU) 2021/522.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

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

OBJECTIVES, SCOPE AND ACTIVITIES

With this action, HERA will contribute to the "*EFSD+ Guarantee Agreement Accelerator Human Development (HDX)*" between EIB and the Commission, which is a Global Gateway initiative that facilitates investment in equitable access to safe, effective, quality and affordable

essential vaccines, medicines and health technologies and enables a better environment for health systems in low- and middle-income countries, contributing to preparedness and more efficient health crisis response.

It is expected that this action contributes to the technical assistance agreement between the Commission and the EIB linked to the "*EFSD+ Guarantee Agreement Accelerator Human Development (HDX)*". Therefore, the funds will be managed by DG INTPA via cross sub-delegation, with EIB as the implementing entity.

EIB is the best placed institution to implement this action due to its extensive experience in the area, the necessary convening powers, and the established relationships with the remaining members of the "*G7 Surge Financing Initiative for MCMs*", including the U.S. DFC, the DFIs, and the IFC. It is expected that it will leverage its founding role in the G7 Surge Financing Initiative for MCMs to further develop it, ensuring a coordinated, cohesive approach by the Secretariat's management. Finally, EIB has a proven track record in management of actions in the field of MCMs and innovative funding mechanisms (e.g. action CP- CO-23-09 under 2023 EU4Health work programme).

Activities under this action include:

- supporting the G7 DFI Surge Financing Initiative on MCMs' secretariat on its managing role, including, but not limited to, coordination of the group's actions, reporting and accounting, and dissemination of results;
- facilitating the establishment of seven financing initiatives envisaged for MCMs' procurement, manufacturing, and delivery, specifically:
  - Liquidity facility for donor financing;
  - Bridge facility for self-financing;
  - Working capital facility for LMIC manufacturers;
  - Volume guarantee for LMIC manufacturers;
  - R&D financing for LMIC manufacturers;
  - Loan for supply chain/service delivery enterprises;
  - Loan guarantee for supply chain/service delivery enterprises.
- setting-up a funding pilot for the next UNGA in (tentatively) September 2025, likely focused on countries in Africa, Latin America, and the Caribbean.

Additionally, this action will support the mitigation of risks coming from emerging threats, especially (albeit not only) originating in LMICs, by developing a wide set of innovative funding tools for MCMs accessibility and availability.

Finally, by fostering international cooperation from major development banks and associated entities, this action will contribute for a coordinated approach in both preparedness and crisis situations, streamlining procedures and further reducing barriers to essential, lifesaving MCMs.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

a) Support for the G7 Surge Financing Initiative for MCMs;
b) Development and testing of innovative financing tools and concepts for the availability and accessibility of MCMs in LMICs;
c) Ensuring of a faster response during outbreaks, avoiding cross-borders spillovers and reducing the risk of pandemic outbreaks; and
d) Strengthening of the Union's role and visibility as a key player in Global Health affairs.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CO-25-85	Q3-Q4/2025	EUR 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Indirect management	Co-delegation type II to DG INTPA	EIB

CP-CA-25-86 The economic case for strengthening public health prevention, preparedness and response to biological and chemical hazards

POLICY CONTEXT

The adoption of Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU[185] and the regulations extending the mandates of the European Centre for Disease prevention and Control ('ECDC')[186] and the European Medicine Agency ('EMA')[187] in 2022 laid the ground for a renewed, coordinated and robust approach to EU health security.

The implementation of Regulation (EU) 2022/2371 is ongoing, further strengthening the Union prevention of preparedness for and response to all health threats, including those of chemical, biological, environmental, and unknown origin, applying an all-hazard approach. The Early Warning and Response System ('EWRS') is being scaled-up to better support all-hazard threats reporting and to facilitate exchanges among Member States in relation to health emergencies which - together with the reinforced Health Security Committee - will improve health crisis management. The EWRS will also be interlinked with other EU alert and information systems e.g., on animal diseases, consumer products, radiological-nuclear emergencies, to ensure a better detection and management of all health threats.

In line with Regulation (EU) 2022/2371, EU and EEA countries have already completed a first cycle of reporting on national prevention, preparedness, and response planning in 2023 and ECDC with other Union agencies are assessing them in 2024. The preparation of a Union prevention, preparedness and response plan on health is underway.

In this context the Organisation for Economic Co-operation and Development ('OECD') will support strengthening public health prevention preparedness and response to biological and chemical hazards through economic case analysis. 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

185 OJ L 314, 6.12.2022, p. 26.

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

187 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).

implement this action. The OECD analysis on the economic aspects of strengthening public health prevention of preparedness for and response to biological and chemical hazards is needed to help countries be better prepared to scale up investment in this area, some lessons may be more widely applicable also to nuclear and radiological threats so countries will be able to use their scarce resources more efficiently in their work on all hazard preparedness. 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 Regulation (EU) 2022/2371 and implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health (Article 3, point (b), of Regulation (EU) 2021/522), through the specific objective defined in Article 4, point (b), of Regulation (EU) 2021/522.

The current action will support the Commission and EU/EEA countries in the implementation of Regulation (EU) 2022/2371 by bringing the economic dimension and making a case for continued investment in prevention, preparedness and response.

OBJECTIVES, SCOPE AND ACTIVITIES

The main objective of the proposed project is to help EU/EEA countries and other countries associated to the EU4Health Programme to scale up investment in prevention of preparedness for and response to biological and chemical threats; some lessons may be more widely applicable also to nuclear and radiological threats.

The action will analyse both the disruptive health and economic effects of biological and chemical hazards and the return on investment of the public health response to the considered threats. The project will also make the case for strengthening interaction between public health authorities and other relevant government actors, such as security and civil protection authorities. The geographical scope of the project will be on EU/EEA and other countries associated to the EU4Health Programme.

Main activities:

a) building on existing work, further identification and review of the most likely biological and chemical threats that the Union may face in the next decade;
b) identification of the current policy landscape and resource gaps in dealing with biological and chemical threats, including the complementary analysis of the level of preparedness for these threats (building on the obligatory assessments under Regulation (EU) 2022/2371) vis-à-vis identified best practices and international standards;
c) analysis of the health and economic impact of the most likely and/or disruptive identified threats, calculating the health and economic impacts of a selected set of biological and chemical hazards including the cost of inaction, both in terms of human health and the economic impact of the considered threats;
d) analysis of best practices for prevention of preparedness for and response as well as resilience to biological and chemical threats and their cost of scaling up, particularly looking at the factors that made the intervention a best practice and assessing the costs of transfer to other EU/EEA and other countries participating in the EU4Health Programme and of scaling-up; and
e) improving cooperation between public health authorities and other relevant governmental agencies, such as ministries of the interior and civil protection.

EXPECTED RESULTS AND IMPACT

The project will produce the following outputs:

a) a publication reporting the results from the work of the different work packages. This will represent the main written output of the project;
b) a policy brief summarising the key high-level messages from the main report in a format suitable for senior and executive policy makers;
c) country notes (2-pagers) for all countries covered, with country-specific findings and options for actions;
d) country-specific policy briefs for the countries selected for the national workshops. The policy briefs will further develop the country notes to provide additional insights and provide the basis for discussion and activities taking place during the national workshops;
e) the organisation of one physical and several online joint meetings of key actors regarding cross-border health threat preparedness and response in Europe such as the Health Security Committee and the ECDC National Focal Points for Preparedness together with the OECD EGEPH and the OECD High-Level Risk Forum throughout the project to exchange views and will identify common ground; and
f) the organisation of country-specific workshops (e.g. 5-6) where discussion will take place at the national level, involving a larger number of experts and authorities, to discuss practical actions to strengthen public health prevention of preparedness for and response to biological and chemical threats through the transfer of best practices.

The impact of the action is expected to be that countries will be better prepared to scale up investment in prevention of preparedness for and response to biological and chemical threats; some lessons may be more widely applicable also to nuclear and radiological threats.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CP-CA-25-86	Q3/2025	EUR 1 000 000
Procedure type	**Implemented by**	**Entity**
Indirect management	DG SANTE	OECD

CP-CA-25-87 Prevention of the entry of the dengue, chikungunya and Zika transmitting Mosquitoes

POLICY CONTEXT

The adoption of the Regulation on Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU[188] and the regulations extending the mandates of the European Centre for

188 OJ L 314, 6.12.2022, p. 26.

Disease prevention and Control ('ECDC')[189] and the European Medicine Agency ('EMA')[190] in 2022 laid the ground for a renewed, coordinated and robust approach to EU health security.

The implementation of Regulation (EU) 2022/2371 is ongoing, further strengthening the Union prevention, preparedness for and response to all health threats, including those of environmental origin. Regulation (EU) 2022/2371 specifically indicates One Health as instrument to facilitate actions and promotes tackling the impact of Climate change on health.

In line with the Regulation, EU and EEA countries have already completed a first cycle of reporting on national prevention, preparedness, and response planning in 2023 and ECDC with other Union agencies will assess them in 2024. The preparation of a Union prevention, preparedness and response plan on health is underway.

The current action will support the Commission and Member States in the implementation of Regulation (EU) 2022/2371, specifically on the monitoring and mitigation of the impact of climate change on health, with a focus on vector-borne diseases. Several countries are experiencing changes into the seasonality of vector-borne diseases as well as the introduction and expansion of vectors carriers of emerging vector-borne diseases, due to climate change.

The European centre of Infectious Diseases Prevention and Control has been working on surveillance of vector-borne diseases. Since 2014, ECDC is involved in collaboration with the European Food safety Agency ('EFSA') in several joint projects on vector surveillance. The current one, vectorNet[191] which is establishing a network of medical entomologists and public health professionals, working in the field of vector-borne diseases across Europe and the countries surrounding the Mediterranean Basin.

In accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522, the ECDC is the eligible entity to implement this action. The award of the action to ECDC is duly justified by its crucial leadership, a convening and coordination role in strengthening multilateral cooperation and in steering preparation and response to public health emergencies. Therefore, the ECDC is the sole entity with the required expertise and capacity to implement this action.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action supports the implementation of Regulation (EU) 2022/2371 and implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health (Article 3, point (b), of Regulation (EU) 2021/522) through the specific objectives in Article 4, points (b), (i), (j) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The project aims to support mediterranean and their neighbouring countries to improve their capacity to implement proper mosquito surveillance, and to establish a plan for their control based on data on resistance to current regulated and available larvicides/biocides to control mosquitos with a focus on Aedes spp that are carriers of dengue, Zika and chikungunya viruses. The ECDC work would be generating national plans to scale up investment in prevention and

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

190 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).

191 https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/vector-net;

preparedness for and response to environmental threats with lessons widely applicable to EU Mediterranean countries with already presence of invasive mosquito species and those neighbouring countries of introduction due to climate change as based on the data generated by vectorNet project. A survey carried out among all the EU/EEA countries by DG SANTE in April 2024 showed that several Member States as areas in need of support vector surveillance, vector control including resistance testing capacity. This action is expected to also complement action "CP-g-25-02 Direct grants to Member States' authorities for the scaling up of national systems for vector threat detection and control capacities", through the national plans to be developed within this action.

The main activities are:

a) supporting countries to strengthening vector surveillance allowing early detection of establishment or geographical expansion of invasive mosquito species (with a focus on Aedes species);
b) guiding response using vector (mosquito)-control activities as complement to, or as alternative to Sterile Insect Technique ('SIT') through the use of chemicals/biocides for adult and larvae population;
c) strengthening capacity to test for resistance to chemical/biocides agents in Member States to be able to implement appropriate mosquito-control measures, establishing coordination between the environmental, animal and public health authorities facilitating the enacting of a One Health approach;
d) providing data related to determinants of health to national public health surveillance systems; and
e) generating case studies to guide vector surveillance and response via traditional vector control techniques for generating the evidence needed for a coordinated policy actions by the Commission in the area of mitigation of health threats risks.

EXPECTED RESULTS AND IMPACT

The project will deliver the following outputs:

a) a report on the results from the work of the different work packages;
b) a policy brief summarising the key high-level messages from the main report in a format suitable for senior and executive policy makers; and
c) country notes (2-pagers) for all the EU/EEA/EFTA countries with country-specific findings related to the chosen actions.

As expected impact, Member States with already presence of Aedes mosquito species and those neighbouring those countries more at risk due to climate change, will be better prepared to scale up investment in prevention preparedness for and response to environmental threats mitigating the effect on health of climate change.

This action contributes to the implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health threats, on detection, prevention, and response to One Health approach.

Lastly, this action complements and strengthens the action funded under the 2024 EU4Health work programme (CP-CA-24-8) by providing evidence not only on the use of SIT as vector control tool but also on the use of traditional vector control ones, besides facilitating action "CP-g-25-02 Direct grants to Member States' authorities for the scaling up of national systems for vector threat detection and control capacities" through supporting countries preparing national plans/list of actions fitting their needs and the evidence collected by the ongoing project vectorNet, also coordinated by the ECDC.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CP-CA-25-87	Q3-Q4/2025	EUR 600 000
Procedure type	**Implemented by**	**Entity**
Indirect management	DG SANTE	European Centre for Disease Prevention and Control

CR/CV&NCD-CA-25-88 Fostering healthy longevity and promoting lifelong prevention

POLICY CONTEXT

The Union is facing a huge challenge related to its ageing population and the impact on society. An impressive rise in life expectancy has been observed across Member States in the last decades. Improvements in living and social conditions, advancements in health care and general economic progress have all led to an increasing number of European citizens living longer lives. Yet many of them live with chronic diseases and have to manage multiple morbidities at the same time. Although the OECD[192] has made a strong case for increasing spending on health promotion and disease prevention measures as it is cost-effective, health spending remains overwhelmingly focused on curative care, with only 3% of total health spending going toward prevention on average. (2017[193], 2022[194], 2024[195] OECD "Health at a Glance" reports).

The State of Health 2023 synthesis report[196] highlights 3 key messages: (i) the need for mental health reforms; (ii) the need for a multi-sectoral approach to tackle health inequalities; (iv) investments in public health, disease prevention and health systems should remain a key priority in the medium term.

The Union's population is ageing and that comes with consequences for health policy, including on healthy longevity, non-communicable diseases, including neurodegenerative diseases[197].

In fact, non-communicable diseases, such as cardiovascular diseases and diabetes, represent 80% of the health burden. Therefore, it is essential to support Member States and citizens in this area as it is the core of the health and financial burden of disease.

192 How much do OECD countries spend on prevention?", OECD Health Working Papers, No. 101, OECD Publishing, Paris, https://doi.org/10.1787/f19e803c-en.

193 OECD (2017), Health at a Glance 2017: OECD Indicators, OECD Publishing,Paris, https://doi.org/10.1787/health_glance-2017-en.

194 OECD/European Union (2022), Health at a Glance: Europe 2022: State of Health in the EU Cycle, OECD Publishing, Paris, https://doi.org/10.1787/507433b0-en.

195 OECD/European Commission (2024), Health at a Glance: Europe 2024: State of Health in the EU Cycle, OECD Publishing, Paris, https://doi.org/10.1787/b3704e14-en.

196 State_2023_synthesis-report_en.pdf (europa.eu).

197 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on The European Health Union: acting together for people's health (COM(2024)206 final).

This burden can best and most efficiently be addressed via prevention, through which 70% of it can be avoided. Prevention efforts must therefore be ramped up through the entire lifespan, starting with pregnancy and early childhood and reaching out to the elderly.

The positive objective of a healthy lifespan for all and of a healthier ageing population brings opportunities and challenges for Member States that will only grow in importance in the future. Broad ranging policy and legislative changes at Union and national level are needed to react to both long-standing and new and emerging challenges in an ageing population.

The fourth high-level meeting of the UN General Assembly on the prevention and control of NCDs[198] will increase awareness on the importance of addressing NCDs. WHO will play a key role in taking forward action following any political commitments.

WHO has the required and unique extensive experience in capacity building and training across countries as well as a unique repository of knowledge and expertise on disease prevention and healthy ageing to support the Member States and implement the action.

A comprehensive, multi-sectoral and lifelong prevention approach to healthy ageing that is based on evidence-based action is needed to support individuals' potential for healthy longevity. Healthy longevity is influenced by the physical and mental capacities of individuals, the environment in which they live, and the interactions among them. Therefore, a comprehensive approach to healthy longevity and lifelong prevention should go beyond public health and strongly include other key policy areas. The Commission's Communication on a comprehensive approach to mental health[199] recognises that mental health is an integral part of health, and that health determinants, such as use of tobacco and alcohol, and environmental, social and commercial determinants all have an important impact on mental health. Under flagship 8 ('Children Health 360') of the Communication, the Commission is developing a prevention toolkit focusing on prevention and addressing the link between mental health and key health determinants[200].

Lifelong prevention provides opportunities for health promotion and disease prevention throughout the entire lifecycle, from early life all the way until the later days of life. This is key to adding healthy life years and must consider the determinants of health including commercial and socio-economic determinants.

In 2023, the Expert Group on Public Health ("PHEG") identified the main priorities and actions on public health challenges for the period 2024-2026. Health promotion and socio-economic determinants of health were considered to be the most relevant, followed by mental health, cancer and the prevention of non-communicable diseases. Working on vaccine-preventable diseases and vaccination was also identified as a priority. In 2023, the priorities of the Public Health Expert Group focused on mental health, and on health promotion and prevention of non-communicable diseases in 2024. The focus of the PHEG's work in 2025 will be on healthy longevity, lifelong prevention of diseases, vaccine-preventable diseases and vaccination, as well as specific communicable diseases, such as TB, HIV/AIDs and hepatitis. The Commission will support the collection of best and promising practices via the EU Best Practices Portal.

This action supports the implementation of "Healthier Together – EU Non-communicable diseases initiative" and Europe's Beating Cancer plan and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a)

198 On the road to 2025

199 https://health.ec.europa.eu/publications/comprehensive-approach-mental-health_en.

200 2024 EU4Health work programme, action DP/CR-CA-24-26 Promoting a comprehensive, prevention-oriented approach to children's health.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to support the efforts of the Member States to foster healthy longevity, and promote lifelong prevention of non-communicable, with a specific focus on cardiovascular diseases.

This action complements and synergises with the joint action (DP-g-25-XX) on 'Lifelong prevention for a healthy life, including through screening – focus on cardiovascular diseases', through collaboration, coordination and knowledge from the WHO Regional Office for Europe.

Through experience from past actions (e.g. JA ImpleMENTAL[201]), Member States consider that the technical support and guidance from international organisations, such as WHO and OECD, in the preparation and implementation of joint actions, provides significant value to the action.

WHO, in close cooperation with the Commission, will be requested to provide capacity-building support for Member States through training and cross-national learning, by sharing expertise on healthy longevity, lifelong prevention of non-communicable diseases, to increase skills and knowledge at policy and practice level.

WHO will support the design and implementation of reforms in public health policy approaches with the aim of increasing investment and impactful actions on prevention and including health promotion in sectors beyond health, improving health literacy and harnessing the use of digital tools.

Specifically, WHO will be requested to provide technical support that can also be activated and directly used by Member States at national level, as well as policy advice, and to develop reference and guidance documents to support Member States in their efforts to reach the health-related UN Sustainable Development Goals, in particular goal 3 to ensure healthy lives and promote well-being for all at all ages, and any new targets agreed under the UN framework. This support will be provided in the context of reducing the use of tobacco and emerging products, the harm of exposure to second-hand smoke and aerosols and harm due to the use of alcohol.

The specific activities to support the joint action will include:

- support for the transfer and implementation of best practices and piloting of promising practices and other innovative approaches on health promotion and lifelong prevention of non-communicable diseases, focusing on cardiovascular diseases;
- provision of expert knowledge on the capacities and competencies needed and on how to maximise the sustainability of public health systems reforms to focus on prevention and early detection of non-communicable diseases, in particular of cardiovascular diseases;
- sharing country-specific knowledge and advice on strategies, action plans and roadmaps to drive reforms in public health policy approaches;
- building the capacity of the Member States in promoting healthy longevity, through policy dialogues, training programmes, workshops and similar activities.

[201] The third Health Programme ('3HP'), Joint Action on Implementation of Best Practices in the area of Mental Health ('JA ImpleMENTAL').

WHO will also be asked to collaborate closely with OECD and UNICEF on the delivery of these activities.

The activities will include a horizontal dimension that focuses on the specific needs of vulnerable groups (e.g children and young people, LGBTIQ populations, refugees/migrants, displaced people from Ukraine, Roma, drug users, prisoners).

The activities should also include an equity dimension and aim at reducing inequalities.

EXPECTED RESULTS AND IMPACT

The projects will produce the following outputs:

a) tailored support (policy guidance and technical assistance) to Member States, Norway and Iceland in developing and implementing evidence-based actions and policies for the prevention and management of non-communicable diseases, with a focus on cardiovascular diseases;
b) capacity-building activities (e.g. workshops, training programmes) among policy-makers and technical staff to support the development and management of public health policies and plans;
c) support to Member States, Norway and Iceland in the collection of data on effective policies and programmes;
d) technical support for the implementation of the Joint Action joint (DP-g-25-XX) on 'Lifelong prevention for a healthy life, including through screening – focus on cardiovascular diseases'.

Through this action, WHO will complement the efforts of the Member States in the joint action on lifelong prevention for a healthy life, including through screening – focus on cardiovascular diseases. Specifically, it is expected to strengthen the impact of the joint action's results, both on the ground and at policy level. It will also foster synergies with relevant WHO action on lifelong prevention and healthy longevity.

Technical support from WHO is expected to make a significant contribution to support Member States to develop and implement reforms in public health approaches and to design and implement ambitious and impactful measures to foster healthy longevity and promote lifelong prevention.

WHO will regularly inform and discuss progress with the Commission and will be invited to engage in the Expert Group on Public Health and/or in activities linked to the joint action on healthy ageing and lifelong prevention of non-communicable diseases, focusing on cardiovascular diseases.

Through this action, support will be given to Member States in their efforts to reach the health-related UN Sustainable Development Goals, in particular goal 3, and WHO targets on non-communicable and any new targets under the UN framework, as well as new and emerging challenges of an ageing population.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CR/CV&NCD -CA-25-88	Q3/2025	EUR 2 000 000

Procedure type	Implemented by	Entity
Indirect management	DG SANTE	WHO

CR/CV&NCD-CA-25-89 Investing in health promotion and disease prevention across the lifespan

POLICY CONTEXT

In the EU, the number of people aged above 65 that will need (long-term) health care and treatment will increase substantially over the next few years, putting direct pressure on national health care systems and on the health workforce. There will be consequences for the sustainability of health care financing as demand for health care services as well as the overall lifetime health care expenses will increase over the lifetime, challenging the sustainability of public budgets overall. Furthermore, many older people will need welfare and social assistance to go about their daily lives. Due to a fast-ageing population and low birth-rates, governments will be faced with increased costs for social services, pensions and quality healthcare.

Prevention is key to avoid ill health and achieve a high level of well-being effectively and efficiently. Despite this being a well-known fact, only small fractions of health care budgets, political attention and stakeholder engagement are dedicated to prevention. The share of spending on prevention in current health expenditure plateaued below 3% across the Union over the period 2014-2019. Spending on preventive care rose to 3.5% in 2020, driven in particular by increased spending on disease detection programmes. The share of spending on prevention in 2021 further increased to 6% of total health spending across the Union due to increased spending on immunisation programmes triggered by the pandemic.

In order to provide convincing information that can be useful in decision-making, it is essential to update and generate more detailed evidence on the health, financial and economic rationale for prevention, in order to promote decisive change also beyond the health sector. The economic case for a prevention approach is strong and clear as noted in the Health at a Glance: Europe 2016, the first product of the State of Health in the EU cycle of knowledge brokering, revealed that across the EU, deaths from major non-communicable diseases translate into around 3.4 million life years lost, or EUR 115 billion in potential economic loss each year. Not surprisingly, a 2017 systematic review of public health interventions found a median return on investment of 14.2 to 1, meaning that every EUR 1 spent can generate total savings of over EUR 14 overall. Addressing harm due to use of alcohol would save 2.6% of total healthcare expenditure on average in Member States. Addressing overweight would save 2% of total health expenditure.

Through the combined effects of overweight in the population on life expectancy, health expenditure and the labour market, GDP will be 3.3% lower on average in OECD countries[202]. There is a need to update the evidence base for increased spending on prevention efforts. This will support evidence-based decision-making for increased and effective spending on preventative healthcare.

Vaccination is a powerful disease prevention tool, including in a life-course perspective. On 21 June 2024, the Union's Health Ministers adopted, upon a proposal from the Commission, a proposal for a Council Recommendation[203] on vaccine-preventable cancers under the Europe's Beating Cancer Plan. Vaccine-preventable cancers are cancers caused by infection with Human papillomaviruses ('HPV') and Hepatitis B virus ('HBV'). The Council Recommendation on vaccine-preventable cancers will support Member States in boosting the uptake of HPV and HBV vaccination through a set of recommendations. A key recommendation to Member States is to introduce or strengthen the implementation of HPV and HBV vaccination programmes to

202 The Heavy Burden of Obesity: The Economics of Prevention, OECD.

203 Council Recommendation of 21 June 2024 on vaccine-preventable cancers.

boost cancer prevention as part of national immunisation programmes, including by providing vaccination free of charge and/or fully reimbursing related costs for those for whom vaccination is recommended, in line with national vaccination recommendations, and by ensuring access and promoting uptake for groups at high risk and/or in disadvantaged situations. As announced in the Council Recommendation, the Commission will support Member States in their decision-making on this matter by supporting the development of modelling tools and analysis to estimate the cost-effectiveness of preventing cancers caused by HPV and HBV infection by vaccination. A joint action with the key purpose of contributing to the implementation of the new Council Recommendation will be launched under the 2024 EU4Health work programme, accompanied by projects deriving from a parallel call for proposals.

The OECD has a crucial leadership and coordination role in global health and can provide the necessary expertise and capacity to implement this action.

This action supports the implementation of "Healthier Together – EU Non-communicable diseases initiative" and Europe's Beating Cancer plan and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a), of Regulation (EU) 2021/522), through the specific objectives defined in Article 4, points (a) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will further support the economic case for increasing investment in health promotion and prevention of NCDs to improve population health. It will also support the implementation of the Council Recommendation on vaccine-preventable cancers.

The OECD will be requested to provide an update of the current estimates for the budget spent on prevention in the Union, and on the health burden and expenditure attributable to key determinants, and to improve the current models used to estimate such figures. This information is key to trigger positive decision making outside the health sector.

The OECD, in close cooperation with the Commission, will also be requested to provide strategic advice to Member States on how to incorporate in their national decision-making regular estimates of the cost of tobacco and emerging products use, alcohol and unhealthy diets for national health systems and the country's GDP. Through modelling tools and analysis, the OECD will estimate the cost-effectiveness of prevention tools, including vaccination, t, of interventions to address the use of tobacco and emerging products, harm due to alcohol and unhealthy diets and physical inactivity.

In addition, the OECD will be requested to estimate the cost-effectiveness of preventing cancers caused by HPV and HBV infection by vaccination in Member States, taking national specificities into account.

The OECD is expected to work closely with other international organisations to ensure synergies and complementarities.

EXPECTED RESULTS AND IMPACT

The project will produce the following outputs:

a) reports on the economic case for increasing investment in health promotion and prevention of non-communicable diseases in Member States, Norway and Iceland;
b) reports presenting updates for the current estimates for the budget spent on prevention in the Union;

c) reports on the cost-effectiveness of preventing cancers caused by HPV and HBV infection by vaccination in Member States, Norway and Iceland;
d) reports estimating the cost-effectiveness of prevention tools; and
e) capacity-building activities (e.g. workshops, tailored discussions) to support the Commission and Member States, Norway and Iceland in health promotion and the prevention of non-communicable diseases.

The OECD is expected to support Member States in identifying and implementing cost-effective measures to prevent NCDs and vaccine-preventable cancers. It will support Member States in addressing the health and economic burden of key public health challenges (NCDs including cancer) by promoting effective prevention policies and activities.

The OECD will support the case for increasing investment in health promotion and the prevention of NCDs and of vaccine-preventable cancers, and in this way contribute to the efforts of the Member States in addressing the challenges faced by an increasing burden of NCDs, including cancer, and an ageing population.

Through these activities OECD will support Member States' efforts to achieve the Sustainable Development Goal 3 and the 2025 WHO targets for non-communicable diseases, in particular by providing the evidence, strategic advice and support for implementation of relevant actions.

This action supports the joint action and will be implemented in synergy with the WHO action on 'CR/CV&NCD-CA-25-17' Fostering healthy longevity and promoting lifelong prevention.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CR/CV&NCD-CA-25-89	Q3/2025	EUR 2 000 000
Procedure type	**Implemented by**	**Entity**
Indirect management	DG SANTE	OECD

HS-CA-25-90 Preparation of 'Health at a Glance: Europe 2026', Country Health Profiles 2027 and Synthesis Report 2027 under the 6th cycle of the State of Health in the EU project

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 Organisation for Economic Co-operation and Development ('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.

The need to regularly develop and make use of high-quality data and analysis for health policymaking has become even more acute following the COVID-19 pandemic. In addition, comparable and robust data can help countries improve the effectiveness, accessibility, and resilience of their national health systems. In this context, the project provides a useful compass

to identify health challenges and health system weaknesses and strengths, and to improve information, expertise, and the exchange of best practices.

Following five successful cycles, the sixth 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 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 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), 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

Based on the revamped design of the fifth project iteration (2024-2025), included in the 2023 EU4Health work programme (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), the 2026-2027 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, including data visualisation activities.

The main activities and deliverables that are to be carried out are the following:

a) 'Health at a Glance: Europe 2026' – a new edition with two new thematic chapters and updated sections of health indicators, including for candidate countries, data allowing;
b) Country Health Profiles 2027 – a new edition of the 29 profiles produced in the previous cycle (for the 27 Member States plus Norway and Iceland)[204];
c) State of Health in the EU – Synthesis Report 2027. This will be a new edition of the previous cycle's Synthesis Report with new findings stemming from the Country Health Profiles 2027;
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 (2024-2025) project cycle.

EXPECTED RESULTS AND IMPACT

In the short term, the State of Health in the EU cycle will support the Member States by strengthening the analytical base on the performance of their health systems and contribute to evidence-based policymaking. 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.

[204] We do not cover the nine candidate countries (Albania, Bosnia and Herzegovina, Georgia, Moldova, Montenegro, North Macedonia, Serbia, Türkiye, Ukraine) because the WHO does so in their Health Systems in Action Insight series.

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

Topic/sub-topic	Estimated launch date	Budget
HS-CA-25-90	Q3/2025	EUR 2 250 000
Procedure type	**Implemented by**	**Entity**
Indirect management	DG SANTE	OECD

HS-CA-25-91 Preparation of Country Health Profiles 2027 and Synthesis Report 2027 under the 6th cycle of the State of Health in the EU project

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 Organisation for Economic Co-operation and Development ('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.

The need to regularly develop and make use of high-quality data and analysis for health policymaking has become even more acute following the COVID-19 pandemic. In addition, comparable and robust data can help countries improve the effectiveness, accessibility, and resilience of their national health systems. In this context, the project provides a useful compass to identify health challenges and health system weaknesses and strengths, and to improve information, expertise and the exchange of best practices.

Following five successful cycles, the sixth 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, 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 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), 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

Based on the revamped design of the fifth project iteration (2024-2025) included in the EU4Health 2023 work programme (HS-CA-23-45-01 State of Health in the EU – 5th cycle: 'Health at a Glance 2024: Europe', Country Health Profiles 2025 and Synthesis Report 2025), the 2026-2027 project cycle will continue producing a wide array of health systems knowledge-brokering products. On top of the 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, including data visualisation activities.

The main activities and deliverables that are to be carried out are the following:

a) Country Health Profiles 2027 – a new edition of the 29 profiles produced in the previous cycle (for the 27 Member States plus Norway and Iceland)[205];
b) State of Health in the EU – Synthesis Report 2027. This will be a new edition of the previous cycle's Synthesis Report with new findings stemming from the Country Health Profiles 2027;
c) infographics for each of the two products above;
d) update and further development of the web-based data visualisation tools developed as part of the previous (2024-2025) project cycle.

EXPECTED RESULTS AND IMPACT

In the short term, the State of Health in the EU cycle will support the Member States by strengthening the analytical base on the performance of their health systems and contribute to evidence-based policymaking. 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

Topic/sub-topic	Estimated launch date	Budget
HS-CA-25-91	Q3/2025	EUR 1 900 000
Procedure type	**Implemented by**	**Entity**
Indirect management	DG SANTE	WHO

[205] The Country Health Profiles do not cover the nine candidate countries (Albania, Bosnia and Herzegovina, Georgia, Moldova, Montenegro, North Macedonia, Serbia, Türkiye, Ukraine) because WHO does so in its Health Systems in Action Insight series.

HS-CA-25-92 Electronic Product Information for medicinal products

POLICY CONTEXT

Today, there is no harmonised regulatory-approved electronic product information ('ePI') for medicines in Europe.

The development and implementation of ePI supports the Pharmaceutical Strategy for Europe. In particular, Article 63 of the proposed Directive[206], which states that Member States may decide whether the package leaflet shall be made available in paper format or electronically, or both.

This action follows the successful completion of actions HS-g-22-17.08 and HS-CA-24-51, under the 2022 and 2024 EU4Health work programmes, which provided financial contribution to finance 'electronic Product Information ('ePI') for medicinal products' through contribution agreements.

The goal of the action is to establish the necessary tooling, guidance and planning to perform a pilot study for ePI of some real cases of medicines for centrally authorised, and nationally authorised medicines, to initiate the pilot study and analyse its preliminary results and to take the next steps towards implementing use of ePI in routine business.

The development of the tooling, the so-called 'minimum viable product' was completed, and the pilot took place between June 2023 and July 2024 in collaboration with National Competent Authorities from Denmark, the Netherlands, Spain and Sweden.

Following the ePI pilot, the aim is to further support the implementation phase of the ePI initiative. This action will support the work on the implementation of the revised legislation on pharmaceuticals, which is one of the priorities outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare.

In accordance with Article 7(1) and Article 13(1), point (b), of Regulation (EU) 2021/522, the European Medicines Agency (EMA) is the eligible legal entity to implement this action. The EMA plays a crucial role in supporting the Union and Member States in response to the Pharmaceutical Strategy for Europe.

The starting date of actions may be set, where appropriate, prior to signature of the contribution agreement and costs may be eligible before submission of the proposal.

This action implements the EU4Health Programme's general objectives of improving the availability, accessibility and affordability of medicinal products and medical devices in the Union, and crisis-relevant products and of strengthening health systems by improving their resilience and resource efficiency, (Article 3, points (c) and (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c), (f) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

Objectives

a) reinforcing the lessons learnt from the ongoing pilot in four Member States (Denmark, the Netherlands, Spain, Sweden) and possibly extend it to other Member States;

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206 Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM/2023/192 final).

b) transition into the ePI implementation phase, including its use as a tool beyond its core objective as information provider, such as supporting management of medicines shortages and availability of medicines to small markets in the Union;
c) raising the confidence of stakeholders in the commitment of the Union's Medicines Regulatory Network to provision of ePI for all medicines in the Union.

Activities

a) implementation of prioritised functionalities (versioning ePI, versioning Quality Review of Documents (QRD) template, extending import of Fast Health Interoperability Resources ePI with user requirements, business process user interface changes, test automation);
b) support development of Member State requirements: managing translations, support mutual recognition or decentralised procedures, other national level business processes;
c) quality enhancements: user interface, data quality in line with QRD template, etc.;
d) implementation activities: training and knowledge transfer to National Competent Authorities, monitoring and reporting.

EXPECTED RESULTS AND IMPACT

a) action supporting the implementation of the Pharmaceutical Strategy for Europe, including the revision of the general pharmaceutical legislation – Article 63 of the proposed revision of Directive 2001/83/EC[207];
b) positive user experience for marketing authorisation applicants, giving pharmaceutical industry stakeholders the necessary evidence and confidence to invest resources and effort to support ePI implementation;
c) enable access to information in the Union multilingual environment, support wider availability of medicines across the EU/EEA, help mitigate shortages for example of innovative oncological medicines;
d) forward momentum of the ePI initiative, building on what has already been achieved by the EMA, National Competent Authorities and the Commission;
e) high external visibility – high interest for patients, healthcare professionals, industry, EU/EEA countries, international level (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use);
f) Contribution to climate change mitigation by reducing the environmental impact of medicines.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
HS-CA-25-92	Q3/2025	EUR 1 700 000
Procedure type	**Implemented by**	**Type of applicants targeted**

[207] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM/2023/192 final).

Indirect management	DG SANTE	Decentralised Agency (European Medicines Agency)

LIST OF ACTIONS OPEN TO THE PARTICIPATION OF LEGAL ENTITIES FROM THIRD COUNTRIES NON-ASSOCIATED TO THE EU4HEALTH PROGRAMME

Actions open for participation without funding (Article 13(1), (2), (3) of Regulation (EU) 2021/522)**:**

- **CP-g-25-09 Direct grants to EU Reference Laboratories (EURLs) to support their functioning in accordance with Regulation (EU) 2022/2371 on serious cross-border threats to health** – open to laboratories that are legal entities from Albania, Kosovo, North Macedonia, Serbia and Türkiye. As stipulated in Article 15(3) of Regulation (EU) 2022/2371, the designated EURL(s) shall cover cooperation and coordination with existing reference laboratories and networks, including the World Health Organization ('WHO') reference laboratories. The scope of the activities of the EU reference laboratories is thus not restricted to the EU and international cooperation may be sought. Therefore, the possibility to open the call to laboratories, being legal entities from Albania, Kosovo, North Macedonia, Serbia and Türkiye is necessary for the achievement of the objectives of the action for the purpose of addressing cross-border health threats as well as the exchange of knowledge and good practice from other regions related to the scope and activities of the future EURL(s).

- **HS-g-25-19 Direct grants to Member States' authorities to support the implementation of a common standard for medical product identification and AI capabilities across Member States -** Open to legal entities from Liechtenstein. Using harmonised and structured data in human medicinal products is a necessity for interoperability across systems and a level playing ground with regards to having up to date and adequate information on medical products, use, availability and developments across the Union. The Union acquis on medicinal products has EEA relevance and all EEA countries, including Liechtenstein, are part of the European medicines regulatory network. Thus, it is in the Union interest to involve EEA countries, including Liechtenstein, in this joint action with the aim to harmonise implementation of the Union pharmaceutical acquis.

- **HS-g-25-21 Direct grants to Member States' authorities on quality of medicines and implementation of the pharmaceutical legislation and the Pharmaceutical Strategy for Europe** – This call aims to strengthen the capacity of the EU/EEA National Competent Authorities' audit and GMP inspections system, while investing in training of the auditors/inspectors. It will also include the development of GDP guidelines, as well as the development of a dedicated GDP training course. These actions will thus positively influence the sustainability of each EU National Competent Authority, and the EU/EEA inspectors' Network as a whole, while guaranteeing good quality medicines. It is therefore necessary to open this call to Liechtenstein, as EEA country without association to the EU4Health Programme to strengthen the European Medicines regulatory network based on equivalent GMP and GDP regulatory compliance programme.

- **HS-g-25-25 Direct grant to Member States to provide regulatory or scientific advice to small and micro-enterprises to support development and carrying out of conformity assessment of devices, especially innovative devices, and to facilitate the Union level coordination on medical device safety issues** – The objectives of this

grant are to further implement the Regulations on medical devices by increasing the capabilities of the system both in terms of scientific/clinical capabilities and capabilities in relation to safety issues of medical devices. The Union acquis on medical devices has EEA relevance and all EEA countries, including Liechtenstein, are part of the European medical devices regulatory network. Thus, it is in the Union interest to involve EEA countries, including Lichtenstein, in this joint action with the aim to support the implementation of the Union medical device Regulations.

Actions open for participation with funding (Article 14 (3) of Regulation (EU) 2021/522):

- **CP-g-25-04/05 Direct grant(s) to Africa Centres for Disease Control and Prevention (Africa CDC) and the African Society for Laboratory Medicine (ASLM), and to Asia Pathogen Genomics Initiative (Asia PGI) to support wastewater surveillance for health threats' early detection (HERA)** – open to Africa Centres for Disease Control and Prevention (Africa CDC) and the African Society for Laboratory Medicine (ASLM) from Ethiopia and Duke-NUS Medical School (Duke-NUS) from Singapore, which manages the Asia Pathogen Genomic Initiative (Asia PGI).
  Wastewater surveillance is widely recognized as one of the most powerful tools to both anticipate emergence of infectious diseases outbreaks, as well as assist in the characterization and evaluation of mutations of pathogens and/or their viral evolution, which was recently demonstrated during the e.g. COVID-19 pandemic and the 2022/2023 Mpox outbreak in Europe. Both Africa and Asia remain important hubs for infectious diseases outbreaks occurrences. Notably, in 2024, there was a surge of Mpox cases in the African continent and the emergence of a new Mpox subclade (Ib), preliminary assessed to be more transmissible, conditioning more severe diseases, and disproportionately affecting some vulnerable populations (i.e. children), leading the World Health Organization ('WHO') to declare this outbreak a "*public health emergency of international concern*" ('PHEIC') in August 2024.
  This action is therefore essential to address the current Mpox outbreak, by allowing the early detection of new clusters as well as monitor potential virus mutations, while transversally also contributing to tackle additional risks that other existing and/or emerging life-threatening pathogens, contributing to the protection of the health of the Union's population.
  Therefore, considering the international scope of this outbreak, the notification of imported cases of clade Ib to Europe (while clade II continues to circulate in the EU population), this outbreak constitutes an ongoing 'serious cross-border threat to health' (as defined in art. 3(a) of Regulation (EU) 2022/2371[208]), and therefore this action is eligible under Article 14(3) of Regulation (EU) 2021/522.

[208] Which repelled Decision No 1082/2013/EU of the European Parliament and of the Council.

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

GRANTS

Crisis preparedness

- **CP-g-25-01 Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA)**
  Indicative budget: EUR 20 000 000.

Cancer, Cardiovascular and other non-communicable diseases (CR/CV&NCD)

- **CR/CV&NCD-g-25-16 A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation**
  Indicative budget: EUR 20 000 000.

PROCUREMENT

Crisis preparedness

- **CP-p-25-34 Ever-warm facilities (EU FAB) for vaccines production – the Commission's Health Emergency Preparedness and Response Authority (HERA)**
  Indicative budget: EUR 111 464 590.
- **CP-p-25-35 Manufacturing investments and manufacturing capacity reservation contracts to strengthen supply of medical countermeasures (HERA)**
  Indicative budget: EUR 40 000 000.
- **CP-p-25-36 Support to speed up the development of, access to and/or uptake of medical countermeasures (HERA)**
  Indicative budget: EUR 52 732 652.
- **CP-p-25-37 Purchase, innovation and deployment of medical countermeasures in emergency situations (HERA)**
  Indicative budget for this thematic area: currently no budget allocated. The exact budget for this action will depend on the needs and the specific countermeasure to be procured with a ceiling of EUR 70 000 000 within HERA's budget share for 2025[209]. In the recent past, a similar action was performed with a budget of about EUR 46 000 000[210]. Budget will be mobilised in case of a cross-border public health emergency or potential development of a serious cross-border public health threat or recognised public cross-border health emergency, including caused by any of the priority threats identified by HERA in its threat assessment.

ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT

[209] Total HERA 2025 budget: EUR 357 645 165 (see page 8).
[210] For more details see: HADEA/2022/NP/0014-Supply of Modified vaccinia ankara against monkeypox.

Crisis preparedness

- **CP-CA-25-79 Supporting the development of medical countermeasures against antimicrobial resistance to strengthen global preparedness and response (HERA)**
  Indicative budget: EUR 30 000 000.
- **CP-co-25-80 Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the Invest EU Programme (HERA)**
  Indicative budget: EUR 20 000 000.
- **CP-CA-25-81 Supporting the Development of Dengue Medical Countermeasures, Anticipating Growing Needs in the Union due to Climate Change (HERA)**
  Indicative budget: EUR 20 000 000.