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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 2026**

EU4Health work programme for 2026

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INTRODUCTION

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

The EU4Health Programme contributes to tackling long-term health challenges by building stronger, more resilient and more accessible health systems while paving the way to a European Health Union. It brings EU added value and complements the policies of the Member States to pursue the following general objectives:

- (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 supports the implementation of Union priorities such as the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe², the EU Global Health Strategy, the Medical Countermeasures Strategy³, the Preparedness Union Strategy⁴, and the implementation of Union health legislation, as well as the activities of the Commission's Health Emergency Preparedness and Response Authority ('HERA'). Also, the EU4Health Programme supports measures making the EU health sector more innovative, competitive and resilient having regard to the Strategy for European Life Sciences⁵. The Programme should also

¹ OJ L 107, 26.3.2021, p. 1: ELI: <http://data.europa.eu/eli/reg/2021/522/oj>.

² Including the "Strategic Approach on Pharmaceuticals for the Environment" (COM(2019) 128).

³ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS - Preparing the EU for the next health crisis: a Medical Countermeasures Strategy. [COM\(2025\) 529 final](#).

⁴ JOINT COMMUNICATION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the European Preparedness Union Strategy. [JOIN\(2025\) 130 final](#)

⁵ [Strategy for European Life Sciences - Research and innovation](#).

contribute to the objectives set out in the Commission communication ‘The European Green Deal’⁶, e.g. including its zero pollution objectives⁷.

In particular, the 2026 EU4Health work programme is addressing initiatives included in the mission letters from Commission President von der Leyen to the Commissioner for Health and Animal Welfare⁸ and to the Commissioner for Equality, Preparedness and Crisis Management⁹. Furthermore, it is supporting new measures to improve the health of people in the Union, while ensuring the long-term resilience and competitiveness of the health sector as put forward in the Commission’s December 2025 health package on a proposed Biotech Act, revised rules for medical devices and a Safe Hearts Plan¹⁰.

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, on 5 December 2023 the Commission adopted the 2024 work programme and on 23 July 2025 the Commission adopted the 2025 work programme. Four amendments have been adopted on 12 April 2022¹¹, on 25 July 2022¹², on 25 July 2023¹³ and on 15 November 2024¹⁴.

On 7 February 2024, the European Parliament and the Council reached an agreement on the revision of the Multiannual Financial Framework (‘MFF’) for 2021-2027¹⁵. 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 involved 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 2026 consists of four overarching ‘strands’: (1) crisis preparedness; (2) health promotion and disease prevention; (3) health systems and healthcare workforce; and (4) digital. In addition, there is a fifth, so called “flagship”-strand, which includes cancer, as well as the new priorities for 2025-2029 on cardiovascular and other non-communicable diseases.

⁶ 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](#).

⁷ 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](#).

⁸ [Olivér Várhelyi - European Commission](#).

⁹ [Hadja Lahbib - European Commission](#).

¹⁰ https://commission.europa.eu/news-and-media/news/commission-proposes-new-measures-improve-health-and-healthcare-sector-2025-12-16_en.

¹¹ C(2022) 2470 final.

¹² C(2022) 5436 final.

¹³ C(2023) 5052 final.

¹⁴ C(2024) 7871 final.

¹⁵ [EU long-term budget and to boost Europe's competitiveness](#).

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 programmes¹⁶, policies, instruments and actions, such as Horizon Europe. Through its EU Mission on Cancer¹⁷, Horizon Europe will contribute to the implementation of some of the Europe's Beating Cancer Plan flagship initiatives and actions.

This work programme is aligned with the Strategic Technologies for Europe Platform¹⁸ ('STEP') and identifies the actions and indicative budgets in support of STEP. Proposals meeting the minimum requirements indicated in the conditions of the STEP-relevant call for proposals will receive a STEP Seal.

This work programme sets out objectives and actions, including the resource allocation, for the implementation of the EU4Health Programme in 2026. 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 regions¹⁹, for the purposes of achieving inclusive growth and a gender sensitive approach, where relevant.

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 Programme²⁰, their participation in actions under this work programme will be subject to compliance of their respective national systems with the Union legislation relevant to the specific action such as Regulation (EU) 2016/679 of the European Parliament and of the Council 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 (the 'General Data Protection Regulation')²¹ when treatment of personal data is involved.

The participation of legal entities from third countries that are not associated to the EU4Health Programme is possible where those third countries are listed in the annual work programme in accordance with Article 13(1), point (a)(iii) of Regulation (EU) 2021/522 and if the conditions specified in Article 13(2) and (3) of Regulation (EU) 2021/522 have been satisfied.

¹⁶ 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 (which supported Member States with over EUR 42 billion for health systems resilience, including modernisation of infrastructure, digital health and workforce capacity), Erasmus+ programme and the European Solidarity Corps Programme.

¹⁷ [EU Mission: Cancer - Research and innovation - European Commission.](#)

¹⁸ The STEP Seal is the Sovereignty Seal defined in Regulation (EU) 2024/795: [Strategic Technologies for Europe Platform - European Union \(STEP\).](#)

¹⁹ EU outermost regions located in the Atlantic and Indian Oceans, in the Caribbean basin and in Latin America.

²⁰ [EU4Health programme 2021-2027 – a vision for a healthier European Union - European Commission.](#)

²¹ OJ L 119, 4.5.2016, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>.

LEGAL BASIS

Regulation (EU, Euratom) 2024/2509²² 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, 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 2026

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 2026 is indicated in Table 2.

TABLE 1: BUDGET LINES

BUDGET LINES	2026 (in EUR)
06 06 01	680 684 742
TOTAL	680 684 742²³

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.

Grants²⁴ 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).

Procurement²⁵ 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	2026 Budget (in EUR)
Direct management	625 157 039
of which grants	270 020 000
of which procurement	352 547 039

²² OJ L, 2024/2509, 26.9.2024, ELI: <http://data.europa.eu/eli/reg/2024/2509/oj>.

²³ Including the estimated amount of contributions from associated EEA/EFTA countries to the EU4Health Programme as well as estimated contributions from third countries associated to the EU4Health Programme.

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

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

of which for other expenditure	2 590 000
Indirect management (contribution agreements)	55 527 703
TOTAL	680 684 742

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

TABLE 3: BUDGET BY ACTION AREAS

STRANDS AND AREAS OF ACTION	2026 budget (in EUR)
1. CRISIS PREPAREDNESS (CP)	429 695 911
HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA)	395 189 008
ANTIMICROBIAL RESISTANCE	500 000
HEALTH SECURITY PREPAREDNESS ACTIONS	34 006 903
2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)	47 095 000
ONE HEALTH ACTIONS	250 000
HEALTH INEQUALITIES IN PEOPLE WITH INTELLECTUAL AND DEVELOPMENTAL DISABILITIES	450 000
MENTAL HEALTH	1 000 000
TOBACCO CONTROL POLICY	1 910 000
EUROPEAN REFERENCE NETWORKS	42 250 000
HEALTH POLICY PLATFORM	525 000
SCIENTIFIC COMMITTEES, EXPERTS' GROUPS	710 000
3. CANCER, CARDIOVASCULAR AND OTHER NON-COMMUNICABLE DISEASES (CR/CV&NCDs)	28 588 000
CANCER ACTIONS	8 588 000
EU CARDIOVASCULAR HEALTH PLAN –Safe Hearts Plan	20 000 000
4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)	111 030 000
PRIMARY CARE AND HEALTH WORKFORCE	2 500 000
IMPLEMENTATION OF THE HEALTH TECHNOLOGY ASSESSMENT REGULATION	13 850 000
IMPLEMENTATION OF THE PHARMACEUTICAL LEGISLATION AND STRATEGY ²⁶	12 945 000

²⁶

Including reimbursement of expert participating in Commission controls and audits in the pharmaceutical field and annual contribution and membership fee to the IPRP and ICH.

CRITICAL MEDICINES	40 000 000
BIOTECH ²⁷	13 900 000
IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS	9 500 000
IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO MEDICAL DEVICES ²⁸	15 835 000
CROSS-BORDER HEALTHCARE	300 000
HEALTH UNION FELLOWSHIP PROGRAMME	1 400 000
EU GLOBAL HEALTH STRATEGY	100 000
EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES	700 000
5. DIGITAL (DI)	46 150 000
IMPLEMENTATION OF THE EUROPEAN HEALTH DATA SPACE REGULATION	44 150 000
AI IN HEALTHCARE	2 000 000
6. OTHER ACTIONS	18 125 831
COMMUNICATION ACTIVITIES ²⁹	4 260 000
TRANSLATION SERVICES	120 000
IT RECURRENT ACTIVITIES ³⁰	10 100 831
ORGANISATION OF CONFERENCES	600 000
OPERATING GRANTS FOR HEALTH NGOS	1 800 000
EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA) EXPERT EVALUATORS AND MONITORS ³¹	790 000
ENLARGEMENT CONFORMITY STUDY	425 000
PEER REVIEW FOR MEDICAL DEVICES	30 000

²⁷ Other actions in the 2026 work programme will have a positive impact on the biotech ecosystem (e.g. further strengthening the Medicines Regulatory Network).

²⁸ Including the Joint assessment of Notified Bodies.

²⁹ Including SANTE and HERA budget.

³⁰ Including SANTE and HERA budget.

³¹ Including SANTE and HERA budget.

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 bodies³².

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-financing³³. 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 costs³⁴. 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 costs³⁵.

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 framework³⁶, 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 as reviewed in 2026. 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

³² Article 201(5) and (6) of Regulation (EU, Euratom) 2024/2509.

³³ Article 193(1) of Regulation (EU, Euratom) 2024/2509.

³⁴ Article 8(3) of Regulation (EU) 2021/522.

³⁵ Article 8(4) of Regulation (EU) 2021/522.

³⁶ [Programme Performance Statement for 2025](#).

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

A. GRANTS

1. CRISIS PREPAREDENESS (CP)

CP-g-26-01 Call for proposals on the European Hub for diagnostics development and scale-up (DG HERA)

POLICY CONTEXT

The COVID-19 pandemic exposed critical gaps in the Union's diagnostic preparedness. Scaling up Polymerase Chain Reaction ('PCR') testing in the early stages of the outbreak was time-consuming, patients frequently experienced long waiting times, and it took approximately one year for the EU common framework for rapid antigen tests to be established. These bottlenecks reflected deeper structural gaps: fragmented national laboratory capacities, shortages of reagents and consumables, and the absence of pre-established EU-level coordination mechanisms for diagnostic test validation and deployment. Together, these factors undermined health authorities' ability to mount an effective and timely response during the critical early stages of the outbreak.

To contribute to the 100 Days Mission³⁷ for diagnostics and to be better prepared vis-à-vis new emerging pathogens, Europe urgently requires a robust infrastructure for rapid testing at the point-of-need that are quickly adaptable, scalable, affordable, easy to use, and that leverage artificial intelligence where appropriate. This crucial need has also been identified by other international stakeholders such as the International Pandemic Preparedness Secretariat ('IPPS') and the Coalition for Epidemic Preparedness Innovations ('CEPI').

Especially in the case of an emerging pathogen/disease X epidemic outbreak, where pathogen-specific tests will not be available yet, Europe must have the capacity to quickly adapt diagnostic platforms, ideally within days of availability of the pathogen sequence, and rapidly scale access to testing and manufacturing to support the 100 Days Mission goals.

Developers of new diagnostic tests may face significant challenges in evaluating the performance of their tests, particularly during the early stages of an emerging outbreak, when access to well-characterised clinical specimens, pathogen sequence data and representative variants may be limited. Accordingly, improved coordination and support for the evaluation and validation of new, innovative tests, such as access to specimens and reference panels, across the Union, would shorten their time-to-market.

Beyond supporting test developers, Europe would benefit from increased coordination between clinical diagnostic laboratories to prepare for rapidly implementing new assays during a pandemic outbreak. While national and EU Reference Laboratories ('EURLs')³⁸ provide essential public health monitoring and guidance, their number and mandate reflect their function as specialised reference centres, and are not designed to provide direct operational support the thousands of decentralised clinical laboratories across Member States that would

³⁷ The 100 Days Mission is an aim to be able to develop and deploy safe, effective diagnostics, therapeutics, and vaccines within the first 100 days of a pandemic (*in* [100 Days Mission Report – IPPS](#)).

³⁸ EU Reference Laboratories (EURLs) for Public Health are specialized centres coordinated by the ECDC created under Article 15 of [Regulation \(EU\) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU](#), "to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States".

need to pilot and/or implement new diagnostics within days or weeks of an outbreak of a pandemic. Enhanced cooperation for this purpose could provide logistical and facilitated access to clinical specimens for clinical and analytical studies by combining the collective specimen repositories of participating laboratories and offer implementation support to local clinical laboratories testing and/or adopting new assays.

Another barrier to rapid diagnostic response in an outbreak is scaling up manufacturing, which is especially challenging for small and medium-sized enterprises ('SMEs') developing novel diagnostic tests. Therefore, support for establishing and scaling production lines from experienced industry partners could facilitate the timely production of as many tests as required.

Finally, as innovative, market-driven diagnostics are rarely available at the immediate onset of a health crisis, the Union requires robust mechanisms to surge testing capacity during the critical initial weeks of a pandemic.

Building on relevant existing projects (e.g. from Horizon Europe or EU4Health), this action aims to create and operationalise the European Diagnostics Hub announced in the Commission's Medical Countermeasures Strategy³⁹ to strengthen diagnostic preparedness and response across the Union, as well as support industrial and competitiveness objectives in the field of medical countermeasures' diagnostics.

As this action aims to strengthen diagnostics preparedness within the operational timeframe of the 100 Days Mission, the participation of legal entities established in Switzerland and the United Kingdom is assessed as necessary for the achievement of the action's objectives under points (c) and (d) below, within the meaning of Article 13(2) of Regulation (EU) 2021/522. Specifically, these objectives require facilitated access to clinical specimens and reference panels for test validation, and manufacturing surge capacity for rapid production scale-up, mobilizable within days to weeks of an outbreak. Switzerland presents a unique diagnostics manufacturing capacity for standard infectious disease testing that is not easily replicated within the Union alone, while the UK's strong expertise in Disease X diagnostics platforms (e.g. metagenomics), together with its research and biobanking facilities for high-risk pathogens (and forefront research in the use of emerging technologies for MCM development, such as AI) is similarly difficult to find within the Union. Without the participation of entities from these two countries, the 100 Days Mission timeframe would be significantly compromised. On this basis, and within the limits of this assessed necessity, entities from Switzerland and the United Kingdom are eligible to participate in the projects as associated partners without funding, in accordance with Article 13(2) and (3) of Regulation (EU) 2021/522, without prejudice to the additional alignment and coordination benefits their participation may also provide under the remaining objectives.

This action contributes to the achievement of 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 (a), (b), and (c), of Regulation (EU) 2021/522).

³⁹

[COM \(2025\)529 final](#) - Communication from the Commission to the European Parliament, the Council, the European and Economic Social Committee and the Committee of the Regions on preparing the EU for the next health crisis: a Medical Countermeasures Strategy.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to create a European Hub for diagnostics development, validation, and manufacturing scale-up, combining excellence in research and development with industrial capacities. It will be launched as an open call for proposals targeting diagnostic developers and manufacturers, spanning SMEs to large industrial operators, working with academic institutions and complemented by specialist regulatory expertise.

The European Diagnostics Hub will need to develop a strategic diagnostic readiness plan for the 100 Days Mission for diagnostics in Europe and subsequently deliver on:

- a) Identification and development of Target Product Profiles that support meeting the 100 Days Mission for Diagnostics in Europe. They should address the Commission's priority threats for medical countermeasures, with a focus on respiratory viruses as well as other viral pathogens⁴⁰ identified in its Health Threat Prioritisation 2026 Assessment for Medical Countermeasures⁴¹, and subsequent iterations.
- b) Acceleration of innovation for modular diagnostic platforms that are rapid, low-cost, multiplexed (where relevant), scalable and/or quickly adaptable to a new pathogen to meet diagnostic needs in a Disease X scenario, aligned to relevant Target Product Profiles.
- c) Support for activities related to technical, analytical and clinical development of diagnostic devices' prototypes, focusing on the Commission's priority threats for medical countermeasures (including from other EU-funded projects), in particular new or innovative rapid point-of-care tests, including for self-testing (e.g. lateral flow assays or nucleic acid amplification tests). This could include, for example, supporting logistical access to specimens and reference panels via relevant partners, the design of protocols for clinical or analytical studies, or the facilitated access to existing EU biobanks and sample providers. During epidemic/pandemic outbreaks, the network should enable facilitated access to clinical specimens for test validation, leveraging existing collective sample repositories of participating laboratories, as well as providing manufacturers associated to the network with accelerated access to clinical specimens and validation support; while during preparedness periods, the network should also function as a standing infrastructure providing manufacturers - particularly SMEs - with facilitated access to clinical specimens and structured support for performance evaluation studies. Facilitation of pathogen-agnostic pilots and simulation exercises testing inter-organisational frameworks for the rapid deployment of harmonised laboratory-developed tests should also be fostered. Where reference laboratories are concerned, coordination should build on, and demonstrate complementarity to, existing EURLs structures for *in vitro* diagnostics and for public health.

⁴⁰ While the need to cover priority viral pathogens is the focus of this action, coverage of chemical or biological (C-, B-) threats in the CBRN domain and antimicrobial resistance related threats, will also be considered in scope and eligible for funding. This may include, for example, toxins or bacterial agents considered CBRN threats.

⁴¹ [SWD\(2026\) 1 final](#) - Comprehensive 2025 Health Threat Prioritisation Assessment for medical countermeasures.

- d) Manufacturing preparedness support to diagnostic development projects (including EU-funded projects) focusing on the Commission's priority threats. Where possible, such support should involve industry partners with significant production and market expertise and be provided from the early stages of development, to ensure that supported diagnostic devices are designed for manufacturability and production scalability. This could include, for example, surge plans to move rapidly to high-volume production in the case of an outbreak, technology documentation, or expert advice on procurement and reimbursement, logistics, or distribution aspects.

Furthermore, this action could also provide for regulatory readiness support⁴² to innovative diagnostics supported directly by the hub or previously supported through EU funding, where these address the Commission's priority threats for medical countermeasures. Additionally, the hub can also provide for a small component supporting preparedness for regulatory submissions, especially by SMEs, through e.g. mock exercises, open workshops, guidance sessions, or simulation activities. Where appropriate, these activities could be organised in cooperation with notified bodies and/or national competent authorities and/or the expert panel for *in vitro* medical devices⁴³, in full respect of their respective mandates and independence.

Given the need to accelerate innovation for modular diagnostic platforms that are rapid, low-cost, multiplexed (where relevant), scalable and/or rapidly adaptable to new pathogens/disease X scenario, the beneficiary will be allowed to provide support to parties in accordance with Article 207 of the Financial Regulation⁴⁴. This model has been successfully applied in EU-funded R&D and support actions, including CEPI and the Pandemic Preparedness Partnership⁴⁵ grants under Horizon Europe, and this action will build on that established framework to pilot its application to diagnostic innovation with early-stage manufacturing readiness.

The beneficiary may award one or several grants to third parties, as single applicants or in consortia, to fund development, innovation and early-stage manufacturing readiness activities for modular diagnostic platforms and enabling technologies. Financial support may be provided to legal entities established in EU Member States, as well as in other eligible third countries under this action as defined in the call and in the grant agreement.

Financial support to third parties is one of the primary activities under objective b) given the fast-evolving nature of the diagnostic technology landscape and the need to respond to emerging platform innovations that may arise during the lifetime of the action. The maximum amount of financial support that may be provided per action shall not exceed EUR 2 000 000⁴⁶, which shall also be the maximum limit received by each third party. This maximum amount per third party is justified by the substantial costs associated with the development and early-stage manufacturing readiness of innovative modular diagnostic platforms. The total amount allocated to financial support to third parties under this action shall preferably not exceed EUR

⁴² Support activities include e.g. clarifying applicable regulatory requirements and pathways, and should not be seen as constituting a pre-assessment, certification or preferential regulatory treatment.

⁴³ [IVD expert panel - Public Health - European Commission](#).

⁴⁴ [Regulation \(EU, Euratom\) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union](#).

⁴⁵ BE READY - Pandemic Preparedness Partnership (PPP) grant funded under [the 2023-2025 HE work programme](#) call HORIZON-HLTH-2024-DISEASE-17.

⁴⁶ However, if the objectives of the action would otherwise be impossible or overly difficult (and duly justified in the proposal) the maximum amount may be higher.

15 000 000⁴⁷. The criteria for determining the exact amount of financial support per third party, including the allocation methodology and selection criteria, shall follow any conditions established in the call and detail, shall be indicated in grant agreement and, where applicable, further elaborated by the beneficiary during project implementation, subject to prior approval by the Commission before any call for proposals is launched. The beneficiary shall report on all financial support provided to third parties, including the identity of recipients, amounts awarded, and activities funded, in the periodic reports submitted under the grant agreement.

The topics and scope of calls for financial support to third parties shall respond to the needs identified in the strategic diagnostic readiness plan developed under this action and shall be agreed *ex ante* with DG HERA to ensure alignment with the Commission's priority policy objectives for medical countermeasures and pandemic preparedness.

The European Diagnostics Hub is expected to engage with other relevant EU-funded initiatives, including the BE READY Partnership for Pandemic Preparedness, EU Research and Technology Infrastructures (e.g. ERINHA⁴⁸ or BBMRI⁴⁹), and the EU reference laboratories. Collaboration with JRC is also welcomed.

Furthermore, where appropriate, the Hub may engage with other international programmes as well as relevant partners (e.g. WHO's i-MCM-Net⁵⁰) to draw on their expertise and ensure strong international alignment.

This action should include feedback and reporting mechanisms to the Commission on the main challenges encountered during implementation, along with evidence-based recommendations on how these could be addressed at EU and Member State level.

EXPECTED RESULTS AND IMPACT

This action is expected to strengthen Europe's diagnostic readiness and resilience against serious cross-border health threats, by building the scientific, industrial and structural foundations needed to ensure the timely availability of high-quality diagnostics for outbreak response and clinical and public health decision-making, notably it will:

- a) Contribute to better preparedness and early response by enabling faster development, validation and deployment of high-quality rapid diagnostics for serious cross-border health threats, including Disease X.
- b) Increase the availability, accessibility and uptake of rapid and modular platform diagnostic solutions across the Union, including innovative platforms.
- c) Improve coordinated validation and regulatory readiness activities, coordinating and, where appropriate, complementing activities of regulatory actors such as notified bodies and national competent authorities, as well as the expert panel for *in vitro* medical devices, and existing national and EU reference laboratory structures for IVDs and public health.
- d) Strengthen Europe's competitiveness, strategic autonomy, and security in diagnostics through improved EU-based manufacturing capacity.

⁴⁷ However, if the objectives of the action would otherwise be impossible or overly difficult (and duly justified in the proposal) the maximum amount may be higher.

⁴⁸ [European Research Infrastructure on Highly Pathogenic Agents](#).

⁴⁹ [Home - BBMRI-ERIC](#).

⁵⁰ [Global Diagnostic Coalition \(WHO\)](#).

To maximise translational impact, this action is expected to ensure structured and meaningful engagement of a wide number of relevant industrial actors (including diagnostics developers, manufacturers, and SMEs) as associated partners either via the onset and/or through a transparent accession scheme defined *ex ante* in the governance framework and open to new participants throughout the duration of the action.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for proposals – CP-g-26-01	Q4/2026	EUR 30 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Private, academic, and public bodies active or with adequate expertise in the field of diagnostic development, validation, manufacturing, or regulatory affairs

CP-g-26-02 Call for proposals on ‘a laboratory network for medical countermeasures (MCMs)’ (DG HERA)

POLICY CONTEXT

As stated in the Medical Countermeasures Strategy⁵¹, strong surveillance as well as rapid identification and alerting of health threats are essential to ensure early development and deployment of appropriate medical countermeasures that can minimise the impact of public health crises.

In addition, the COVID-19 crisis, during which multiple variants emerged, highlighted the need for the EU to have the capacities to rapidly detect and characterise emerging pathogens, and to translate such related scientific data (e.g. biological characterisation) into operational recommendations for MCMs.

To address this need, the Commission launched the action ‘CP-g-06.5 Call for proposals: supporting a HERA laboratory network’ under the EU4Health 2021 Work Programme⁵² (DURABLE project⁵³, ending in January 2027). To date, the DURABLE project has delivered important biological intelligence to the Commission, including new data and knowledge on the protective effect of zoonotic influenza vaccines, and on the ability of routinely used molecular assays to detect the mpox Clade I.b at the time this clade was emerging in Africa. This

⁵¹ [Preparing the EU for the next health crisis: A Medical Countermeasures Strategy - Public Health](#)
⁵² [C\(2022\) 5436 final](#).
⁵³ [Home - DURABLE](#).

intelligence supported the Commission in identifying gaps and vulnerabilities in the current MCM arsenal, and to take decisions on MCM innovation, procurement or stockpiling.

Since the start of the DURABLE project in 2023, the Commission has designated ten EU reference laboratories (EURLs)⁵⁴ for public health under Regulation (EU) 2022/2371 on serious cross-border threats to health⁵⁵. There are important linkages to be made between the DURABLE project and the EURLs for public health, as their activities are covering complementary fields: surveillance, notification and reporting of communicable diseases (EURLs) and characterisation of threats to inform the update, development, or provision of MCMs (DURABLE project). Thus, this action should have a *'bridge function'*: it should ensure the continuation of the activities carried out so far by the DURABLE project consortium while supporting the Commission to prepare the institutionalisation of these activities, including through the integration of activities, where possible, in the framework of the EURLs for public health⁵⁶.

The action will focus on the health threats prioritised by the Commission for MCMs⁵⁷, and/or other relevant emerging new threats that could pose a risk to Europe and that might require interventions by the Union or its Member States to ensure the availability of and access to medical countermeasures.

This action will support the policy priority to enhance EU preparedness for future health emergencies, with a particular emphasis on improving the EU capacities to perform in-depth characterisation of emerging pathogens, and to inform the update, development or timely provision of medical countermeasures.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The action will inform the Commission's decision making with respect to the development, procurement and/or stockpiling of relevant MCMs. These include medicines and medical devices used for the detection and diagnosis, prevention, and treatment of health threats, as well as relevant goods and services for vector threat detection and control. It will provide timely and

⁵⁴ These EURLs were established to provide support to national reference laboratories, and to promote good practice and alignment by Member States on diagnostics, testing methods and the use of certain tests for ensuring the uniform surveillance, notification and reporting of diseases by Member States. The EURLs for public health cover a wide range of communicable diseases and have responsibilities in various areas, including scientific advice and technical assistance.

⁵⁵ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁵⁶ The following areas will notably be assessed when considering institutionalisation into the EURL framework: a) laboratory intelligence (early warning/unusual observations); b) development, validation and roll-out of testing methods outside IVDR (related to emerging pathogens); c) contribution to integrated EU risk assessments; d) training in lab capacity and capability building (including general lab system strengthening).

⁵⁷ [Comprehensive 2025 Health Threat Prioritisation Assessment for medical countermeasures](#).

tailored assessments informing MCM decision-making, including specific analyses and studies mandated by the Commission (e.g. biological characterisation and outbreak modelling).

The action should be operational both in preparedness and crisis times and shall ensure that its governance system allows for close alignment and coordination with relevant EURLs for public health as well as the ECDC. To this end, it should have the capacity and flexibility, to rapidly and effectively support the response at Union level when a crisis emerges. In preparedness time, it will deliver data, information, knowledge and innovative tools supporting the Union's threat assessment and intelligence gathering function relevant to medical countermeasures. In case of a potential or declared crisis, it will deliver data, information, and knowledge supporting the Commission's MCM response to the health threat of concern.

The action should generate information relevant to medical countermeasures, including for global health threats that emerge outside the EU. To this end, the action should have a global coverage, with the support of applicants with branches and/or subsidiary members in non-EU countries, especially the ones neighbouring the EU outermost regions, in order to collect intelligence on global threats including through biological samples. In this context, this action should align with the global health architecture, in particular the WHO Pandemic Agreement and its upcoming annex on the pathogen access and benefit-sharing system (currently under negotiation).

This action is expected to cover at least the following activities:

- a) operating a network of laboratories, research, and public health institutes with a wide geographical and global reach, ensuring a governance system that closely coordinates with the relevant EURLs for public health as well as the ECDC;
- b) supporting the Commission's assessment and prioritisation of health threats to inform decision-making on medical countermeasures, both in preparedness and in crisis situations, and building also on existing research and technology infrastructures, including via:
 - investigating disease mechanisms, transmission pathways, and immune responses for priority pathogens; and
 - performing in-depth biological characterisation and assessment of priority pathogen and vector traits.
- c) supporting the Commission's assessment of MCMs in development and those on the market through studies that go beyond licensing/authorisation requirements;
- d) laying the foundations and providing horizontal, pre-competitive enablers and tools that create the conditions for the further development of relevant MCMs; and
- e) advancing modelling approaches to support MCM interventions across the full preparedness and response cycle, including scenario-based modelling grounded in pathogens' traits, to anticipate MCM demand and needs and to inform their strategic planning and management.

In parallel this action should support the Commission in identifying the activities to be integrated into the framework of the EURLs for public health, where possible, and in developing an action plan supporting the integration of relevant activities into the framework of the EURLs for public health.

Activities should draw on relevant intelligence about human, animal and environmental threats, endorsing a One Health approach, and other relevant areas. The activities should harness the power of innovative tools, like metagenomics and AI. Furthermore, ways to facilitate access to

samples and/or strains of interest should be investigated, and relevant procedures should be established in accordance, coordination and collaboration with applicable international rules and systems.

Activities will be performed in close collaboration with the relevant Commission services and agencies, in particular with regards to activities under article 15 (*‘EU reference laboratories’*) of Regulation (EU) 2022/2371⁵⁸; activities under articles 5 (*‘Operation of dedicated networks and networking activities’*) and 10 (*‘Identification of emerging health threats’*) of Regulation (EC) 851/2004⁵⁹, and activities under other relevant EU policy areas (e.g. One Health).

Additionally, these activities will be defined and carried out in close coordination and synergies with relevant stakeholders and other ongoing actions, in particular the ECDC epidemiological surveillance system and the work carried out by the EURLs for public health.

This includes complementing and supporting the work of the European Hubs, such as the already established EU Vaccine Hub and the forthcoming Diagnostic and Therapeutic Hubs, as well as the BE READY European Partnership for Pandemic Preparedness. Synergies can include the establishment and integration of data and information-sharing mechanisms on threats and scenarios, and the sharing, where relevant, of upstream, cross-cutting enablers and tools that support these actions.

EXPECTED RESULTS AND IMPACT

This action is expected to result in the following outcomes:

- a) in-depth biological characterisation of health threats and assessment of their related medical countermeasures, supporting the Commission’s decision-making on MCMs (including on MCM innovation, procurement, and stockpiling) during preparedness and crisis times;
- b) a readily available network of laboratories with established and optimised procedures and means - such as key infrastructure, resources and procedures - that will allow the action to switch from preparedness into emergency mode and respond rapidly in crisis times, in synergy with the EURLs for public health and other relevant actions, such as the European Hubs and research and innovation European partnerships;
- c) enhanced integration between the project outputs and the EURL framework, supporting long-term institutionalisation of activities within the EURLs for public health, where possible.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for proposals – CP-g-26-02	Q4/2026	EUR 18 000 000

⁵⁸ [Regulation \(EU\) 2022/2371](#) of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance).

⁵⁹ [Regulation \(EC\) No 851/2004](#) of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control.

Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Public and non-profit and for-profit private laboratories and research institutes

CP-g-26-03 Direct grant to support pan-African health organisations to expand the Pathogen Genomics Initiative (‘PGI’) and related activities (DG HERA)

POLICY CONTEXT

The COVID-19 pandemic showed that serious cross-border health threats arising in other parts of the world can have a huge impact on health worldwide, including in the Union. Therefore, the reinforcement of emergency preparedness and response at Union level needs to be coupled with strengthening it at global level.

By bolstering the capacity of pan-African health organisations to detect and respond emerging outbreaks and to strengthen the fight against AMR, the Union is, on the one hand, investing in the prevention of potential future health crises that could also affect European countries as well, while, on the other hand, reinforcing its security by e.g. allowing for the development or deployment of crisis-relevant medical countermeasures. The African continent has suffered several outbreaks of serious cross-border health threats in the last years, including directly causing the declaration of a public health emergency of international concern (‘PHEIC’)⁶⁰ due to Mpox in 2024, supporting the maintenance of the polio PHEIC since 2014⁶¹ as well as the declaration of the PHEIC of Ebola in 2026⁶². Moreover, the continent faces significant challenges with regards to AMR. The need for this action is further reinforced by the geographical proximity and deep-seated historical ties between the African and European continent, which have resulted in a dense network of intercontinental transport, including high-volume air travel corridors that have the potential to rapidly facilitate the rapid movement of pathogens.

In this sense, the COVID-19 pandemic highlighted the critical importance of global genomic pathogen detection, characterisation, and data sharing for the timely detection of emerging pathogens and novel variants, including for informing decision makers on needs related to innovation, procurement and deployment of medical countermeasures. The Africa Centres for Disease Control and Prevention (‘Africa CDC’), through its Pathogen Genomics Initiative (‘PGI’)⁶³, has become a key continental actor in addressing gaps in regional inequities in sequencing capacity and related data infrastructures, e.g. by early deployment of a genomics-based sequencing and bioinformatics laboratories across the continent.

⁶⁰ [WHO Director-General declares mpox outbreak a public health emergency of international concern.](#)

⁶¹ See, for reference, the ‘Statement of the forty-first meeting of the Polio IHR Emergency Committee’ of April 10 2025 ([Statement of the forty-first meeting of the Polio IHR Emergency Committee](#)).

⁶² [Epidemic of Ebola Disease caused by Bundibugyo virus in the Democratic Republic of the Congo and Uganda determined a public health emergency of international concern.](#)

⁶³ [Africa Pathogen Genomics Initiative – PGI 2.0.](#)

This action builds on previous EU4Health actions⁶⁴ which established the foundations and partnerships for the PGI and the structure, pilots, and knowledge for wastewater surveillance; and it intends to further reinforce genomic sequencing data sharing capacities and genomic based surveillance systems, as well as contribute to strengthening whole genome sequencing capacities (including via emerging technologies such as metagenomics) of national reference laboratories based in the African continent, particularly for priority epidemic-prone diseases and threats with limited medical countermeasures. The action will also contribute to ensuring the sustainability of these capacities, as well as promote their consolidation by integrating them into national and continental disease control platforms and relevant early warning system for health threats, as envisioned in the EU Medical Countermeasures' *'Global Cooperation and Coordination on MCMs'* chapter and the Team Europe Initiative with Africa on Sustainable Health Security using a One Health Approach.

Thanks to their extensive expertise, previous collaboration with the Commission and consolidated presence on the continent, the most suitable organisations to implement this action are:

- Africa CDC, a pan-African institution under the auspices of the African Union, responsible to coordinate and support African countries in improving public health capacity, disease surveillance, and emergency response across Africa;
- African Society for Laboratory Medicine ('ASLM'), which is the first pan-African society for laboratory professionals endorsed by the African Union, working to improve local access to world-class diagnostic; and/or
- Africa Public Health Foundation ('APHF'), an independent charitable foundation that mobilises philanthropic and private-sector resources to support critical public health initiatives across Africa and, where appropriate, designs and manages specific grants on behalf of continental health institutions.

Africa CDC will have an overseeing role, leveraging on their existing diagnostics stakeholders' network, while the implementation of the specific activities will be led by ASLM and/or APHF⁶⁵. Since these organisations are the only ones possessing the needed tools, network, and knowledge to deliver the expected results within the set timeframe, their participation is necessary for the achievement of the objectives of this action pursuant to Article 13(2) and (5), of Regulation (EU) 2021/522 and they are considered eligible legal entities. Their participation is essential to ensure that the action can be implemented in the African regions, and it is vital to address current and potential health crisis, including PHEICs such as the polio PHEIC, the Ebola PHEIC, as well the 'silent' AMR pandemic, while having the additional benefit of building a more resilient health global landscape and ensuring the long-term protection of both Africa and the EU, including, among others, the prompt deployment of MCMs in the immediate

⁶⁴ These EU4Health-funded actions include CP-g-06.7 ('*Strengthening preparedness and response to cross-border health threats at global level*') under the 2021 Work Programme ([C\(2022\) 5436 final](#)), CP-g-23-22 ('*Direct grant to support the Africa Pathogen Genomics Initiative*') under the 2023 Work Programme ([C\(2022\) 8510 final](#)), CP-g-24-109 ('*Direct grant to support the Africa Centres for Disease Control and Prevention (Africa CDC) and the African Society for Laboratory Medicine (ASLM) in responding to Mpox*') under the 2024 Work Programme ([C\(2024\) 7871 final](#)), and 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*') under the 2025 Work Programme ([C\(2025\) 5148 final](#)).

⁶⁵ ASLM and APHF were the named beneficiaries of the action(s) launched to support the first phase of the PGI initiative.

emergence of a future outbreak. Thus, the costs incurred by the beneficiaries are eligible in accordance 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. The award of a direct grant is duly justified as the beneficiaries identified are the only ones that have the necessary technical competence and degree of specialisation.

Furthermore, for proposals under this action, and exceptionally on the basis of Article 196(2), point (b), of the Financial Regulation, costs incurred from 16th May 2026 onwards, corresponding to WHO's Ebola Bundibugyo PHEIC declaration, may be eligible and may be declared, even if the related activities have been implemented prior to proposal submission.

The proposed action will contribute to strengthening preparedness to respond to serious cross-border health threats in the Union by improving the detection and characterisation of pathogens as well as related genomic interoperable data sharing capacities within the African continent, with the aim to inform MCM development and deployment networks. In particular, close collaboration with DG HERA, ECDC and (where feasible) EU Member States on whole genome sequencing activities is expected. Finally, this action shall also synergise with EDCTP3's projects, as well as the Team Europe Initiative with Africa on Sustainable Health Security using a One Health Approach and its actions⁶⁶.

The action supports the Union's EU's global commitments and health initiatives, and it implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health (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

This action aims to expand and support the long-term sustainability of Africa PGI strengthening the continent's capacity for cross-border through whole genome sequencing, pathogen detection, genomic characterisation, and related data integration, thereby anticipating MCM needs and contributing to global and EU health security, including to address pressing needs such as those linked to the Ebola PHEIC. In particular, this action shall:

- a) expand pathogen detection through diagnostic, whole genome sequencing tools, as well as genomic sequencing capacity in the African continent, including via the use of emerging technologies (e.g. metagenomics and automation systems), enhancing skills and knowledge pertaining to those activities, and strengthen laboratory infrastructure for cross-border surveillance with One Health approaches, such as via ready-to-use laboratories and/or incorporation of animal or environmental samples;
- b) support the establishment of regional diagnostics validation hubs for priority epidemic- and pandemic-prone pathogens;
- c) procure diagnostic tools and other necessary equipment to safely deploy diagnostic workflows (e.g. consumables, ancillary kits, or personal protective equipment) so that they can be rapidly deployed and seamlessly integrated into routine surveillance and outbreak response systems, including for ongoing screening programmes;
- d) provide training activities to ensure the appropriate utilisation of diagnostic capacities;

⁶⁶ E.g. ARILAC ('Advancing Regional Integrated Laboratory Capacity for AMR Control').

- e) ensure the integration of genomic sequencing data into national, continental, and (where relevant) EU- or WHO-based international disease control IT platforms and infrastructures, facilitating data sharing and use for e.g. decision-making on MCM development and/or deployment; and,
- f) promote real time data sharing and governance frameworks aligned with the principles of equity, transparency, accountability, and sovereignty of African data and with the AGARI platform.

This action will institutionalise the PGI network within Africa CDC's framework, contributing to its longer-term operations, in close cooperation with the Commission and other global partners, when relevant.

EXPECTED RESULTS AND IMPACT

The action will contribute to improving continental and global health security by enhancing intelligence gathering and genomics capacities, supporting prompt identification of MCM innovation and deployment gaps and subsequent response. More specifically, expected results will include:

- a) accelerated detection and confirmation of priority pathogens through decentralised, fit-for-purpose diagnostic tools deployed in outbreak-affected and high-risk areas;
- b) strengthened national and regional laboratory networks, with increased numbers of facilities, appropriate equipment, trained laboratory personnel, and operational capacities, including during outbreaks;
- c) enhanced genomic intelligence to support MCM decision-making, including the timely identification of strains, characterisation of chains of transmission, detection of variants of concern, and provision of genomic data to inform the development or adaptation of vaccines, therapeutics, and diagnostics;
- d) improved surveillance networks and geographic coverage of genomic sequencing and AMR monitoring across Africa, including the integration of related data into continental and other relevant data management, reporting, and sharing platform(s);
- e) collaboration and the formation of a multistakeholder African community of practice related to genome sequencing activities (encompassing national, supra-national and international initiatives), including researchers, bioinformaticians, clinicians, epidemiologist and public health professionals; and,
- f) strengthened Africa CDC's PGI framework, ensuring its sustainability and long-term operational capacity.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – CP-g-26-03	Q4/2026	EUR 6 500 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant in accordance with Article 198(1), point	HaDEA	Africa CDC, ASLM, and APHF

CP-g-26-04 Direct grant to support to EU Member States’ authorities for coordinating whole genome sequencing (‘WGS’) activities to strengthen preparedness and response (DG HERA)

POLICY CONTEXT

In 2021, under the DG HERA Incubator Action Area 1⁶⁷, the Commission, alongside the ECDC, initiated a national infrastructure support programme. This programme provided direct grants to EU Member States and EEA countries associated to the EU4Health programme to enhance WGS and real-time polymerase chain reaction (‘RT-PCR’) capabilities, aiming to bolster diagnostics and threat detection. To further support this work, the 2022 EU4Health work programme provided 21 direct grants to Member States, supporting them in establishing WGS and RT-PCR infrastructures and integrating genomics into routine surveillance and outbreak response. During the implementation of these grants, several symposia and workshops on WGS were organised for Member States to showcase the progress of their projects, identify remaining gaps and needs, and agree on a roadmap for sustainability. Finally, to ensure that the programme would cover all relevant Member States, the 2025 EU4Health work programme included an action to allow for the remaining countries to enhance their WGS capacities.

To consolidate and ensure a comprehensive and sustainable implementation and integration of these infrastructures, this joint action will build on the achievements of the abovementioned grants, with a focus on coordination and collaboration, interoperability, data sharing governance and professional skills, while allowing participating countries to define concrete priorities according to the needs across the Union. Furthermore, the specific needs arising from their remoteness of rural and remote regions, EU islands, and EU outermost regions⁶⁸ should be specifically considered and positively ranked.

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. The award of a direct grant is duly justified as the beneficiaries identified are the only ones that have the necessary technical competence, degree of specialisation, and/or legal mandate to implement the expected activities in the Member States.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The focus of this action is to sustain and improve national public health WGS capacities, complemented where relevant by RT-PCR, and to consolidate further integration of genomics-

⁶⁷ [COM\(2021\) 78 final](#) - 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: HERA Incubator.

⁶⁸ [Inforegio - The EU and its outermost regions](#).

based methods into routine disease surveillance and outbreak preparedness and response. The joint action will be implemented by a consortium of interested authorities of Member States and EU4Health associated countries. Activities will primarily target coordination, knowledge exchange and targeted maintenance of capacities, and should address needs related to WGS and/or RT-PCR processes identified at national level by several countries and cross-border.

Building on the results of already implemented projects, the action will complement and extend systems and workflows at national and/or regional levels, with particular attention to the analytical phase and the data-analysis/sharing phase governance. The following list is indicative and non-exhaustive; the consortium of participating countries may select, combine or prioritise activities in line with their needs and capacities, and may cover all areas or focus on a subset. Potential areas of work include:

- 1) Reinforcing coordination of digital and data infrastructure for WGS
 - a) Setting up or improving national IT systems and processes to align with the EHDS regulations, if applicable.
 - b) Propose reusable solutions for the sharing and storage of pathogen typing data and associated epidemiological data.
 - c) Improve the integration and efficiency of national pathogen typing data systems to strengthen national surveillance and EU surveillance, incorporating when applicable, a One Health approach.
- 2) Advancing laboratory and analytical capacity
 - a) Organising technical trainings and knowledge exchange on how to integrate new technologies into WGS workflows for public health purposes (e.g., artificial intelligence, metagenomic sequencing, and/or other technologies).
 - b) Harmonising quality assessment by providing standards for quality assurance/quality control ('QA/QC'), producing datasets for data analysis workflow validation and organising and implementing External Quality Assessments ('EQAs'), in close coordination with the relevant EURLs for public health.
- 3) Enhancing preparedness and scalability
 - a) Updating and testing national scale-up plans to ensure rapid increases in sequencing and analysis capacity during major outbreaks.
- 4) Ensuring sustainability and demonstrating value
 - a) Collecting and sharing cost data for sequencing and diagnostic equipment, reagents, and maintenance to support benchmarking and supplier engagement.
 - b) Conducting health-economic analyses to document the return on investment of WGS for routine surveillance and outbreak response, producing evidence to inform decision-making.

The final set of activities covered and the balance across these areas will depend on the joint proposal put forward by participating countries.

EXPECTED RESULTS AND IMPACT

This action is expected to deliver results that are directed and contribute towards the following outcomes:

- a) in the short/medium term, contribution to the sustained and routine use of national public health WGS capacity for surveillance and outbreak response, with maintained workforce competencies, QA/QC, and timely data sharing;
- b) in the medium term, contribution to strengthened European interoperability and operational readiness, with the ability to rapidly scale-up sequencing and analysis if needed to support the response to serious cross-border health threats; and,
- c) in the medium/long term, contribution to enhanced Union preparedness and response to serious cross-border threats to health, with genomics embedded as a standard, cost-effective public health function that helps keep Europe citizens safe and to inform and accelerate vaccines and therapeutics development.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – CP-g-26-04	Q4/2026	EUR 5 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to Member States (joint action) in accordance with Article 198(1), point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States authorities

CP-g-26-05 Direct grants to Member States' authorities to strengthen EU deployable diagnostic capacities and pre-positioned medical countermeasures for health emergencies (DG HERA)

POLICY CONTEXT

The Union faces an increasingly complex risk landscape: more frequent infectious disease outbreaks, growing CBRN threats (whether accidental, naturally occurring or deliberate) and the cascading effects of climate change, environmental degradation, and geopolitical instability. These trends amplify the probability and potential scale of cross-border health emergencies, demanding a Union-wide approach that is both responsive and forward-looking.

The Medical Countermeasures Strategy³ identifies two complementary gaps that requires addressing. First, the availability of rapidly deployable diagnostic capacity: Rapid Response Mobile Laboratories ('RRML') have demonstrated their critical role in outbreak response (from Ebola and Crimean-Congo haemorrhagic fever ('CCHF') to COVID-19 surge support and humanitarian emergencies) yet their interoperability, standardisation, and equitable distribution across Member States remain uneven. Second, the speed of countermeasure delivery: central stockpiles, while essential, may be inadequate where medical intervention is required within minutes of exposure, as is the case for certain chemical agents. Pre-positioned, ready-to-deploy MCM kits address this last-mile gap.

In 2025, WHO published minimum operational standards and a typology ('MOST') for RRMLs⁶⁹, and the GOARN⁷⁰ Strategic Group for Diagnostic Surge Capacities ('DiSC') is developing a global quality assurance system for a recognised RRML roster. This action builds on those international efforts while advancing the EU's own preparedness architecture under the Preparedness Union Strategy⁷¹ and its all-hazards, One Health, and whole-of-society approach. It also expands and complements the EU4Health 2024 Work Programme⁷² action CP-g-24-13 (*'Direct grants to Member States' authorities: Support to the development of sustainable, forward-looking national and Union stockpiling strategies (HERA)'*).

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. The award of a direct grant is duly justified as the beneficiaries identified are the only ones that have the necessary technical competence, degree of specialisation, and/or legal mandate to implement the expected activities in the Member States and third countries.

Given the action's focus on strengthening deployable diagnostic and medical countermeasure capacities for cross-border health emergencies, including CBRN scenarios, the participation of legal entities established in Albania, Canada, the United Kingdom, and Türkiye, is assessed as necessary for the achievement of the action's objectives, within the meaning of Article 13(2) of Regulation (EU) 2021/522 and should, therefore, be able to participate as associated partners without receiving funding. In detail, the dual-use nature of RRML capacities, and their potential deployment in conflict or high-risk security contexts, requires that operational and technical standards be interoperable with NATO defence and civil-protection frameworks from the outset of development rather than retrofitted afterwards; Albania, Canada, the United Kingdom and Türkiye, as NATO members, hold defence-linked operational protocols and CBRN response expertise that cannot be substituted from within the Union alone, and without their participation the interoperability objective could not be reliably achieved.

This action implements the EU4Health Programme's general objective 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 objective defined in Article 4, points (a), (b), (c), (d), and (j), of Regulation (EU) 2021/522).

OBJECTIVES, SCOPE AND ACTIVITIES

The overall objective is to strengthen the Union's preparedness and response capacity to cross-border health threats (including CBRN emergencies) by enhancing the availability, interoperability, and operational readiness of rapidly deployable diagnostic laboratories, and by enabling the immediate delivery of medical countermeasures at or near the point of need.

The action is structured around two distinct but complementary workstreams, together with a set of shared activities addressing common governance and coordination needs.

Workstream 1: Rapid Response Mobile Laboratories ('RRML')

⁶⁹ [Minimum operational standards and typology for rapid response mobile laboratories](#), published April 28, 2025.

⁷⁰ [GOARN](#).

⁷¹ [EU preparedness union strategy](#).

⁷² [C\(2024\) 7871 final](#).

Building on existing mapping of RRML capabilities and gaps⁷³, this workstream seeks to strengthen RRML capacities across Member States and associated countries by:

- Harmonising technical, operational, and quality standards for mobile laboratory systems, ensuring interoperability with EU preparedness and surveillance frameworks and alignment with ongoing WHO/GOARN standardisation and quality assurance efforts, including the MOST typology.
- Scaling up operational readiness and deployability of RRML capacities, including through technology innovation, procurement of prototypes, training, knowledge exchange, sharing of best practices, and cross-country exercises, fostering a European and international community of practice.
- Enhancing national and EU-level infrastructures for real-time data collection, integration, and use during deployments, ensuring connectivity and operational linkage between mobile and fixed laboratory capacities, and enabling seamless exchange of data, samples, and results.
- Piloting and validating multi-country RRML deployment models across a range of scenarios, including diagnostic access in underserved areas, surge capacity for crisis response, and ancillary functions such as environmental and animal surveillance, within and beyond the EU.
- Promoting the development and uptake of innovative mobile laboratory capabilities, including new modular systems, emerging technologies, and improvements to laboratory, biosafety, security, and communication components, structured around: (i) sensing technologies and field-deployable diagnostic tools; (ii) analytics platforms supporting data interpretation and decision-making; and (iii) system platforms ensuring secure connectivity and interoperability.

Solutions under this workstream should be designed and validated against an evolving risk landscape encompassing naturally occurring, accidental, and deliberate biological threats, including those linked to advances in biotechnology and synthetic biology. Given the dual-use nature of RRML capacities and their potential deployment in conflict or high-risk security contexts, appropriate consultation of relevant defence authorities and, where relevant, international organisations such as NATO, should be ensured. This workstream should actively engage and complement ongoing actions under the Union Civil Protection Mechanism (UCPM)^{74 75}, in particular the European Civil Protection Pool, and the rescEU Emergency Medical Teams (EMT) project, ECDC's EU Health Task Force, GOARN DiSC, and projects under Horizon Europe⁷⁶.

Workstream 2: MCM emergency kits for CBRN and other high-impact health emergency scenarios

This workstream seeks to enable the immediate availability and administration of MCMs at or near the point of need by:

⁷³ E.g. see analysis performed by Horizon Europe project [MOBILISE \(grant nr. 101073982\)](#).

⁷⁴ [Decision nr. 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism](#).

⁷⁵ Under UCPM, RRMLs from Member States committed to the ECPP can be supported to upgrade and/or repair their response capacities via 'adaptation grants'.

⁷⁶ E.g. of projects funded under the call ["HORIZON-CL3-2021-DRS-01-05 - Fast deployed mobile laboratories to enhance situational awareness for pandemics and emerging infectious diseases"](#).

- Designing and validating ready-to-deploy MCM emergency kits tailored to CBRN and other high-impact health emergency scenarios, ensuring clinical relevance, operational feasibility, and rapid usability in the first minutes to hours following an incident.
- Developing scalable and interoperable deployment models for MCM kits across Member States, taking into account different national emergency response structures, regional risk profiles, and logistical constraints, including procurement-based and virtual stockpiling models.
- Strengthening rapid dispatch and last-mile delivery capabilities for medical countermeasures, complementing centralised EU and national stockpiles.
- Strengthening coordination and preparedness of national and regional authorities and emergency responders through joint planning, technical guidance, and targeted training on MCM kit deployment.

Both workstreams share common needs in terms of governance, strategic alignment with EU and international preparedness frameworks (including the Medical Countermeasures Strategy and WHO guidance), sustainability planning, and long-term integration of supported capacities into national and Union preparedness architectures. Activities addressing these shared needs (including joint oversight mechanisms, common reporting frameworks, and cross-workstream knowledge exchange) should be organised at the level of the overall action.

Given the scope and scale of activities envisaged, activities under workstream 1 are expected to represent at least two thirds of the total eligible costs of the action, reflecting the breadth of infrastructure, standardisation, and deployment work required across Member States.

EXPECTED RESULTS AND IMPACT

This action is expected to enhance the EU's capacity to detect, assess, and respond to cross-border health threats in a manner that is rapid, coordinated, and equitable across Member States, by:

- Increasing surge diagnostic capacity that is easily deployable and available for rapid mobilisation anywhere in the Union;
- Enabling faster detection and assessment of outbreaks and biological and chemical threats;
- Enabling immediate delivery and administration of MCMs at or near the point of need, complementing central stockpiles for scenarios requiring intervention within minutes;
- Improving cross-border cooperation, interoperability, and standardisation of mobile laboratory operations and MCM deployment;
- Closing capacity gaps between Member States through shared infrastructures, joint deployment models, and knowledge exchange;
- Promoting a common EU approach to biosafety, data integration, laboratory readiness, and forward-deployed countermeasure logistics.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – CP-g-26-05	Q4/2026	EUR 15 000 000

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

CP-g-26-07 Direct grant to Member States' authorities to enhance public health security in the Union (DG SANTE)

POLICY CONTEXT

The Union is facing an evolving landscape of health threats, where emerging infectious diseases, extreme weather events and security related geopolitical instability can overwhelm national health systems, resulting in significant social and economic losses. The management of emerging hazards requires new skills and capabilities and ensuring the psychosocial resilience of the population remains essential. Thus, the EU health security framework is entering a critical phase: upgraded based on lessons from recent pandemics, it now needs to be fully implemented and operationalised to effectively respond to all types of threats. These developments emphasise the need for stronger, coordinated action to establish a future-proof system that ensures health security across the Union.

This Joint Action ('JA') will be a key component of this broader effort to enhance the Union preparedness and crisis management infrastructure. It aligns closely with the EU Preparedness Union Strategy⁷⁷, the ProtectEU: a European Internal Security Strategy⁷⁸, the EU Strategy on Adaptation to Climate Change⁷⁹, and implements Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health⁸⁰, providing operational support for strengthened capacities at national and Union level to withstand future serious cross-border health threats. It also contributes to the implementation of the World Health Organization's Regional Office for Europe (WHO EURO) 2nd European Programme of Work 2026–2030 ('EPW2')⁸¹ as regards health security in the EU/EEA, to avoid any duplication of efforts and contributes towards implementation of the International Health Regulations.

In accordance with Regulation (EU) 2022/2371 and the enhanced mandate of the European Centre for disease prevention and control ('ECDC') (Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 853/2004 establishing a European centre for disease prevention and control⁸²), ECDC has developed activities such as the Public Health Emergency Preparedness Assessments (PHEPAs), the EU Health Task Force ('EUHTF'), the coordination of European Reference Laboratories in public health ('EURLs'), as well as in the chemical, biological, radiological and nuclear ('CBRN') domain (including on intentional release of biological agents and dual-use biotechnology). ECDC is also active in global health security, including cooperation with enlargement and neighbourhood countries. Relevant actions by the Commission as well as by the ECDC and other EU agencies must be taken into account when developing and implementing this joint action in order to avoid duplication and to maximise synergies.

Against this background, this JA aims to address operational gaps by strengthening governance mechanisms, facilitating sharing of information and peer-learning, enhancing cross-sectoral collaboration, and supporting Member States in building sustainable capacities for prevention of, preparedness for, response to and recovery from health crises that could be caused by a

⁷⁷ [European Preparedness Union Strategy](#).

⁷⁸ [ProtectEU: a European Internal Security Strategy](#).

⁷⁹ [Forging a climate-resilient Europe - the new EU Strategy on Adaptation to Climate Change](#).

⁸⁰ OJ L 314, 6.12.2022, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁸¹ [Second European Programme of Work 2026-2030 \(EPW2\)](#).

⁸² OJ L 314, 6.12.2022, ELI: <https://eur-lex.europa.eu/eli/reg/2022/2370/oj/eng>.

biological, chemical, environmental, unknown or other threats. It takes a system approach connecting the different areas of work across sectors under the health security umbrella.

In particular, this JA enables the participating EU/EEA countries to strengthen and implement their national prevention, preparedness and response planning for health crises based on their national action plans developed in relation to the Public Health Emergency Preparedness Assessments ('PHEPA's) and to seek coherence with the Union prevention, preparedness and response plan for health crises in accordance with Articles 5 to 8 of Regulation (EU) 2022/2371. The JA also responds to calls for the training of healthcare staff and public health staff in particular through interdisciplinary One Health approach, including on preparedness capacities under the International Health Regulations ('IHR')⁸³, in accordance with Article 11. In addition, it will strengthen ECDC's role in assessing EU public health work force capacity and in supporting the countries to respond to health threats, taking into account the role of the EU Health Task Force.

The external dimension of health security is equally vital. The EU Global Health Strategy⁸⁴ and the Global Health Resilience Initiative⁸⁵ aim at strengthening prevention, preparedness and response and early detection of health threats globally. They emphasise that the Union's resilience is inherently linked to resilience beyond its borders. The Global Health Resilience Initiative explicitly refers to the need to pay particular attention to the EU neighbourhood. Involving them in this joint action on health security preparedness will ultimately bring benefits to the Union's collective ability to prepare and withstand to cross-border health threats. Shared vulnerabilities, particularly in neighbouring and enlargement countries, necessitate closer cooperation, mutual support, and the advancement of the One Health approach. Strengthening relationships with strategic partners and boosting collective capabilities against hybrid threats are also key priorities in this JA. In this light, in addition to the EU Member States and the countries associated with the EU4Health Programme, competent public health authorities from Albania, Kosovo⁸⁶, Liechtenstein, Türkiye, Switzerland and the United Kingdom are eligible to participate in the joint action as associated partners without funding in accordance with Article 13(1), point (a)(iii), (2) and (3) of Regulation (EU) 2021/522.

This JA acknowledges that health security is crucial to the Union's overall prosperity and resilience. By integrating governance, preparedness, and external engagement, the JA will contribute to the comprehensive and agile EU health crisis management framework. It represents a concrete step toward closing identified gaps, fostering solidarity among Member States, EEA and other countries participating in the EU4Health Programme, and ensuring that the Union is better prepared to respond to future health crises with unity and strength.

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.

The action is expected to ensure complementarity with on-going actions on crisis preparedness as well as those to be implemented in accordance with new initiatives such as the Medical Countermeasure strategy⁸⁷.

⁸³ [International health regulations.](#)

⁸⁴ [EU Global Health Strategy: Better Health for All in a Changing World - Public Health.](#)

⁸⁵ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Reinforcing global health resilience amidst geopolitical change. COM/2026/197 final.

⁸⁶ This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

⁸⁷ [Preparing the EU for the next health crisis: A Medical Countermeasures Strategy - Public Health.](#)

This action focuses mainly on the implementation of 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), while it also supports strengthening health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522). Specifically it aims at strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-border threats to health, and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange, surveillance, the coordination of voluntary stress testing of national healthcare systems, and the development of quality healthcare standards at national level, specific objectives defined in Article 4, points (a), (b), (e), and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This JA will entail a comprehensive, future-oriented panoply of activities to bolster health security by addressing critical gaps in prevention, preparedness, response, and recovery in line with the all-hazards, One Health, whole-of-government and whole-of-society approaches. Building on the successes of previous EU4Health funded Joint Actions like SHARP⁸⁸, TERROR⁸⁹, UNITED4Surveillance⁹⁰, JA HEROES⁹¹ and JA GHI⁹², and aligned with Regulation (EU) 2022/2371, the EU4Health Programme, the EU Preparedness Union Strategy, the WHO EURO's EPW2 and the IHR, this action aims to reinforce Member States' governance, capacities and resources to prevent, prepare for, respond to and recover from serious cross-border threats to health, enhancing resilience both within the Union and beyond.

This JA will focus on five key areas:

- 1) **Prevention, preparedness, response, and recovery:** including *inter alia* addressing areas of improvement identified during the countries' self-assessment as well as the PHEPAs, supporting the implementation of national action plans to close the gaps and to strengthen capabilities for all-hazards planning and testing, including in the area of biosecurity and through the One Health approach.
- 2) **Civil-military cooperation:** developing interoperability protocols and establishing coordination mechanisms and tools to ensure seamless collaboration during potential crises.
- 3) **Resilience to chemical, environmental, health security related biotoxins, novel and unknown origin and other threats:** establishing adapted preparedness frameworks, enhancing detection capacities, and applying One Health approaches to mitigate complex risks.
- 4) **Contribution to global health security resilience:** reinforcing partnerships with neighbouring/ enlargement countries and relevant international organisations, and addressing shared vulnerabilities, including hybrid threats and disinformation.

⁸⁸ [Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action - SHARP JA | RIVM.](#)

⁸⁹ [Joint Action TERROR: Strengthened Preparedness and Response to Biological and Chemical Terror Attacks - Home page - JA TERROR.](#)

⁹⁰ [Union and National Capacity Building 4 IntegraTED Surveillance - Home - United 4 Surveillance.](#)

⁹¹ [HEalth woRkfOrce to meet healht challEngeS - The project – JA HEROES | Health Workforce Planning Project.](#)

⁹² [European Joint Action to maximise the impact of the EU global health strategy - EU Global Health Impact.](#)

- 5) **Health security governance and workforce strengthening** co-creating sustainable governance models, improving coordination across the Union, national, regional levels, especially focusing on the inter-regional level and investing in a skilled and adaptable (public) health (care) workforce that can be rapidly (re-)deployed, taking into account the role of the EUHTF in situations of health emergencies.

The JA may include the following deliverables, which can be further complemented by additional outputs as decided by the participating entities:

- 1) Interoperability guidelines and protocols on inter-sectoral cross-border preparedness arrangements, such as but not limited to points of entry, civil-military cooperation, biosecurity, etc., and including sectors such as law enforcement and defence;
- 2) Pilot/stress-testing the above guidelines/protocols in the participating countries, for example through targeted simulation exercises and in and after-action reviews;
- 3) Activities and capacity-building actions addressing areas for improvement identified in self-assessments and the PHEPAs under Regulation (EU) 2022/2371 to support the further implementation of the national action plans;
- 4) Preparedness and response protocols for response to cross-border chemical and environmental threats, including large-scale industrial incidents as well as deliberate-release events at Member State and Union level.
- 5) Activities to support the readiness of the health workforce to be rapidly deployed in the events of major health emergencies taking into account the EUHTF, such as but not limited to competency frameworks, cross-border workforce deployment protocols, field epidemiology training, training curricula, and exercises to test surge capacity.

EXPECTED RESULTS AND IMPACT

This action is expected to have the following results and impact:

- a) **Prevention, preparedness, response, and recovery:** by enhancing interoperability and national capacities, the joint action should support strengthened EU health security capabilities and resilience to serious cross-border health threats.
- b) **Civil-military cooperation:** by further developing coordination mechanisms and interoperability protocols, the action will bolster joint operational readiness, including against man-made threats such as military interventions.
- c) **Resilience to chemical, climate, and environmental threats:** by developing new preparedness frameworks to strengthen resilience against environmental and chemical hazards, and by integrating One Health principles, the action will contribute to reducing health system vulnerabilities and protecting populations from complex risks.
- d) **Global health resilience:** by enhancing collaboration with neighbouring and enlargement countries in alignment with WHO EURO's EPW2, the IHR and the EU Global Health Strategy and the Global Health Resilience Initiative, the joint action will support mutual resilience, boost preparedness beyond the EU/EEA countries and improve crisis coordination.
- e) **Health security governance and workforce strengthening** by developing arrangements and investing in training of the healthcare workforce to support possible rapid (re-)deployment in cases of health emergencies, this joint action supports future-ready, competent, flexible and agile workforce enhancing long-term resilience of the health systems and the population, and consistent crisis response capabilities across the Union.

- f) **Overall impact:** by providing and testing/piloting practical tools, addressing the areas of improvement, strengthening networks and supporting capacity building, the action will strengthen EU health security, protect Union citizens, and solidify the Union's leadership in global health crisis management

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grant to Member States – CP-g-26-07	Q4/2026	EUR 24 850 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to Member States (joint action) in accordance with Article 198(1), point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	Member States' authorities

CP-g-26-08 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 (DG SANTE)

POLICY CONTEXT

Article 15(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health⁹³ 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.

Strengthening Europe's defences against cross-border health threats is essential for ensuring 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 outbreaks effectively⁹⁴. 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 years⁹⁵. This action supports the functioning of the next EURL(s) for public health to be designated based

⁹³ OJ L 314, 6.12.2022, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁹⁴ [ECDC-public-health-microbiology-strategy-2018-2022.pdf](#).

⁹⁵ [EU Reference Laboratories for public health - European Commission](#).

on the submission of successful applications under the Calls for Application(s) that were published by DG SANTE in Q1 2026⁹⁶. 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 EURLs are to be considered transnational networks and therefore they are eligible for grants without a call for proposals in accordance with Article 198(1) point (d) of the Financial Regulation.

In the case of direct grants awarded without a call for proposals to transnational networks established 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 costs⁹⁷.

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 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), (h) and (i), 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) were defined by the Calls for Application(s) to designate EURL(s) that were published by DG SANTE in Q1 2026. The activities of this action must be aligned with what was 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).

⁹⁶ 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.

⁹⁷ Article 8(4) of Regulation (EU) 2021/522.

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 Programme⁹⁸.

As stipulated by Article 15(3) of Regulation (EU) 2022/2371, the network of EURLs, operated and coordinated by the ECDC and to which the designated EURL(s) will belong, shall cover cooperation and coordination with existing reference laboratories and networks, including the World Health Organization ('WHO') reference laboratories. Via the network of EURLs, international cooperation may be sought with laboratories based in Albania, Kosovo, Lichtenstein, Türkiye, or United Kingdom for participation in the activities of the EURLs, in accordance with Article 13(1), points (a)(iii), (2) and (3) of Regulation (EU) 2021/522. Upon request from the EURL(s), these laboratories may participate in activities of this grant at their own cost. These laboratories will not be considered eligible participants or included in the grant agreement, either as beneficiaries or as associated partners.

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;
- 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-26-08	Q4/2026	EUR 7 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to designated EU reference laboratories for public health in accordance with Article 198(1), point (d), of Regulation (EU, Euratom) 2024/2509	HaDEA	Designated EU reference laboratories ⁹⁹

⁹⁸ Article 8(4) of Regulation (EU) 2021/522.

⁹⁹ See footnote under policy context on designated EURLs.

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1. HEALTH INEQUALITIES AFFECTING PEOPLE WITH INTELLECTUAL AND DEVELOPMENTAL DISABILITIES

DP-g-26-09 Call for proposals to support action for addressing health inequalities in people with intellectual and developmental disabilities across the EU, focusing on cardiovascular health (DG SANTE)

POLICY CONTEXT

President von der Leyen's political guidelines¹⁰⁰ and her mission letter¹⁰¹ to the Commissioner for Health and Animal Welfare call for the Commission to step up its work on preventive health, particularly for cardiovascular diseases. This echoes the firm recognition and call for action to tackle this public health challenge by the Council of the European Union¹⁰², the European Parliament and stakeholders.

Cardiovascular diseases are the leading cause of death in the EU, claiming 1.7 million lives each year. They also contribute significantly to disability, early retirement, and absenteeism, which lowers the quality of life and reduces life expectancy. These diseases cost the EU over EUR 282 billion annually due to decreased productivity and economic output¹⁰³.

People with intellectual and developmental disabilities experience significant health inequalities that begin early in life and often persist into adulthood. A joint report by the World Health Organization and UNICEF published on 15 September 2023¹⁰⁴, highlights consistent evidence of poorer health outcomes, unmet healthcare needs and reduced access to quality care.

The Safe Hearts Plan addresses the key challenges across the EU related to cardiovascular health, focusing on the special needs of vulnerable population groups, such as people with intellectual and developmental disabilities.

Health inequalities affecting people with intellectual and developmental disabilities extend into adulthood, increasing their risk of non-communicable diseases, in particular cardiovascular diseases, as well as related risk factors such as diabetes and obesity^{105,106}.

In this context, improving early detection, follow-up and prevention for people with intellectual and developmental disabilities is directly relevant to the objectives of the Safe Hearts Plan. Targeted action supports the cross-cutting theme of reaching every citizen by addressing the barriers that prevent this population from benefiting from cardiovascular prevention measures.

The action will build synergies with other Union programmes to enhance coherence and avoid duplication. It will complement Erasmus+, in particular Erasmus+ Sport, by building on results and good practices from projects promoting health through sport and physical activity for people with disabilities. The activity should also seek synergies with relevant research and

¹⁰⁰ [POLITICAL GUIDELINES FOR THE NEXT EUROPEAN COMMISSION 2024–2029](#).

¹⁰¹ [Mission Letter Commissioner-designate for Health and Animal Welfare](#).

¹⁰² In December 2024 the Council adopted [Council Conclusions](#) on the improvement of cardiovascular health in the European Union.

¹⁰³ [Cardiovascular health - Public Health - European Commission](#).

¹⁰⁴ [Global report on children with developmental disabilities](#).

¹⁰⁵ [Global report on children with developmental disabilities](#).

¹⁰⁶ [High prevalence of diabetes mellitus, hypertension and obesity among persons with a recorded diagnosis of intellectual disability or autism spectrum disorder - PubMed](#).

innovation projects funded by Horizon Europe addressing disabilities¹⁰⁷. The action will align with EU4Health priorities and the Safe Hearts Plan, by supporting inclusive approaches to prevention, early detection and care pathways.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to contribute to reducing health inequalities affecting people with intellectual and developmental disabilities by improving access to inclusive, preventive and person-centred health services, with a specific focus on the early detection and management of cardiovascular disease risk factors, in line with the Safe Hearts Plan.

The action will address gaps in prevention, early identification and follow-up of preventable and treatable conditions that disproportionately affect people with intellectual and developmental disabilities, while strengthening health system capacity to deliver inclusive care across the life course.

The scope of the action covers children, young people and adults with intellectual and developmental disabilities, as well as healthcare professionals. Activities will be implemented at EU level, with targeted support in selected Member States, and will be complementary to national policies and initiatives.

Key activities will include:

- the design of tools to enable free and accessible health screenings tailored to the needs of people with intellectual and developmental disabilities, with a focus on cardiovascular risk factors and related non-communicable diseases;
- the development and delivery of training activities for healthcare professionals and community health workers to strengthen skills in inclusive, person-centred and preventive care;
- targeted programmes supporting early development and inclusion of young children with intellectual and developmental disabilities;
- health system assessments in selected Member States, followed by practical inclusion plans and targeted technical support to improve access to preventive care;
- coordination with a corresponding Erasmus+ Sport action to promote physical activity and healthy lifestyles among people with intellectual and developmental disabilities.

Mandatory deliverables will include screening and training tools adapted to the target group, assessment reports and inclusion plans for participating Member States, and a final implementation report summarising results, lessons learned and policy implications.

EXPECTED RESULTS AND IMPACT

The action is expected to improve access to preventive health services for people with intellectual and developmental disabilities through tailored and accessible health screenings, leading to earlier identification and follow-up of cardiovascular risk factors and related non-

¹⁰⁷ For example, the call under Horizon Europe Work Programme 2025: HORIZON-HLTH-2025-03-STAYHLTH-01: Improving the quality of life of persons with intellectual disabilities and their families.

communicable diseases. It will also strengthen the capacity of healthcare professionals and community health workers to deliver inclusive, person-centred and preventive care.

The action is expected to improve awareness among health authorities and service providers of the specific barriers faced by people with intellectual and developmental disabilities in accessing cardiovascular prevention and broader health services. Health system assessments and inclusion plans will support participating Member States in identifying gaps and opportunities for improvement within existing structures.

The action will build synergies with the Safe Hearts Plan and its related actions, including the flagship initiative on the incubator for innovation and integration of artificial intelligence and digital technologies in cardiovascular healthcare, by supporting inclusive approaches to early detection, prevention and care pathways and by helping ensure that emerging digital solutions are accessible and relevant for vulnerable population groups, including people with intellectual and developmental disabilities.

By promoting early detection, physical activity and healthier lifestyles, the action is expected to support better management of cardiovascular risk and contribute to reducing avoidable health inequalities. Overall, the action will support the implementation of the Safe Hearts Plan by advancing its objective of reaching every citizen and ensuring that cardiovascular prevention efforts better address the needs of vulnerable population groups.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for proposals – DP-g-26-09	Q4/2026	EUR 450 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States' public health authorities, academia and education establishments, research institutes, established networks in the field of public health, Civil Society Organisations, associations, foundations, NGOs, social media, press and journalist association.

2.2. MENTAL HEALTH

DP-g-26-10 Call for proposals to address the broader impacts of social media on health and well-being, focusing on the mental health of children and young people (DG SANTE)

POLICY CONTEXT

President von der Leyen's political guidelines¹⁰⁸, Council Conclusions on promoting and protecting the mental health of children and adolescents in the digital era¹⁰⁹ and mission letters to Commissioner for Health and Animal Welfare¹¹⁰ and Executive Vice-President for Tech Sovereignty, Security and Democracy¹¹¹ called for an EU-wide inquiry into the broader impacts of social media and excessive screen time on mental health and well-being, particularly for children and young people, in order to have an evidence-based debate on the issue.

The President of the European Commission, Ursula von der Leyen, also set up a Special Panel of experts to help develop a strong and practical European approach to keep children safe online. Announced in the 2025 State of the Union address, the Panel has brought together young people and experts from across the EU, including in health, neuroscience, psychology, computer science, child rights, and digital literacy.

The action will take into account the outcomes of the work of this Special Panel and will support broader EU mental health efforts, aligning with the ongoing work outlined in the Communication on a comprehensive approach to mental health¹¹².

This action will also ensure close alignment with ongoing Commission initiatives, for instance, that address the digital transition, youth empowerment, and safe online environments, as well as projects funded under the Horizon Europe Cluster 1¹¹³ and Cluster 2¹¹⁴.

Synergies will be developed through coordination with actions under the Digital Europe Programme, in particular the Better Internet for Kids (BIK) Strategy, the European Digital Education Hub, and broader efforts to strengthen digital awareness, online safety, and child protection in the digital sphere. The action will also contribute to the implementation of the Digital Principles Declaration.

In addition, there will be a focus on promoting youth participation, education, and wellbeing in digital environments. Links will be established with Erasmus+ and the European Education Area initiatives to disseminate findings, integrate mental health and digital wellbeing topics into educational settings, and engage young people directly through existing youth networks and dialogue platforms.

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

¹⁰⁸ [Political Guidelines 2024-2029 | European Commission.](#)

¹⁰⁹ [Council conclusions on promoting and protecting the mental health of children and adolescents in the digital era.](#)

¹¹⁰ [Mission letter to Commissioner Várhelyi.](#)

¹¹¹ [Mission letter to Executive Vice-President Virkkunen.](#)

¹¹² [A comprehensive approach to mental health - European Commission.](#)

¹¹³ Cluster 1 Health call topic on [prevention of the harmful effects of using digital technologies on the mental health of children and young adults.](#)

¹¹⁴ Cluster 2 Health call topic on the [impact of the use of digital tools outside school and for communication on educational outcomes and mental health.](#)

(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 proposed action will address the broader impacts of social media on health and well-being, focusing on the mental health of children and young people, and taking into account the results of the Eurobarometer carried out as the first step under an EU-wide inquiry and the work of the Special Panel and other relevant EU initiatives.

Activities:

- 1) **Capacity building:** Conduct workshops and training for researchers, educators/parents, health professionals, civil society actors, and health ministry representatives to enhance understanding and application of health and social media policies (this can include best and promising practices);
- 2) **Digital health awareness:** Co-create educational resources and community initiatives promoting safe social media use and mental well-being, with a focus on children and young people;
- 3) **Multi-stakeholder inquiry and collaboration:** Establish dialogue platforms connecting children and young people, academia, civil society, educators/parents, health professionals and Member States' officials to share best practices;
- 4) **Synergies with existing networks and projects:** Partner with existing projects and networks like the Child Participation Network to incorporate youth perspectives and align efforts with ongoing EU projects such as those funded under Horizon Europe or other EU programmes, and national initiatives.

Deliverables:

- 1) **Capacity building workshops:** A number of workshops/webinars involving all stakeholder groups, with detailed reports documenting outcomes and best practices;
- 2) **Repository of knowledge tools:** accessible and practical guides, policy briefs, and toolkits tailored for children and young people, academia, educators/parents, health professionals, and civil society;
- 3) **Digital health awareness resources:** Training modules and educational content co-developed with stakeholders;
- 4) **Communication platform:** An interactive platform to facilitate ongoing stakeholder dialogue and collaboration, including your people, to provide a space where national authorities can also benefit from shared resources and insights;
- 5) **Progress and impact reports:** Regular updates on the project's implementation, capacity building results, and collaboration effectiveness, including lessons learned.

EXPECTED RESULTS AND IMPACT

This action is expected to contribute to:

- knowledge and impacts: using insights from the action and the inquiry with stakeholders, including the work of the Special Panel;
- stronger stakeholder capacity: improved skills and collaboration to take forward health interventions linked to the impacts of social media and excessive screen time on mental health and wellbeing;
- enhanced digital health awareness: targeted and practical resources promoting safe social media use;

- ongoing collaboration: communication tools enabling continuous stakeholder dialogue;
- synergies with existing networks and projects: alignment with existing networks and projects to amplify youth engagement and impact.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for proposals – DP-g-26-10	Q4/2026	EUR 1 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, established networks in the field of public health, Civil Society Organisations, in particular representing children and young people, associations, foundations, NGOs, social media, press and journalist association; health professional associations.

2.3. EUROPEAN REFERENCE NETWORKS

DP-g-26-11 Direct grants to European Reference Networks ('ERNs'): support for the coordination, management, and operational activities of the ERNs (DG SANTE)

POLICY CONTEXT

The ERNs¹¹⁵ in the field of rare or low-prevalence complex diseases were established in 2017 in accordance with Article 12 of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare¹¹⁶. Currently there are 24 virtual networks connecting specialised healthcare providers across the Union. This action will support the business continuity of the ERNs for the period 2027-2029. It will enable rare disease patients and their health professionals to benefit from the pooling of expertise, knowledge and resources at EU level and to receive the appropriate diagnosis and treatment as well as enhance knowledge generation, training and research in rare diseases, including by building upon relevant projects testing the feasibility and usefulness of complementary actions in this area. It will provide support to the 24 ERNs including their coordination centres for the coordination, management and operational activities of the ERNs, and facilitate the long-term sustainability of ERNs and their better integration into national health systems. It will also support activities connecting Ukrainian competent authorities and healthcare units to the ERNs, taking into consideration the experience of the Rare Diseases Hub Ukraine.

The award of a direct grant as referred to in Article 13(6) of Regulation (EU) 2021/522 is duly justified because ERNs are identified beneficiaries and therefore, they are eligible for grants without a call for proposals in accordance with Article 198(1) point (d) of the Financial Regulation.

In the case of direct grants awarded without a call for proposals to European Reference Networks ('ERNs') 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. Subject to 2027 budget availability, this action may be supplemented with additional funds and duration extended accordingly.

In accordance with Article 196(2), point (a), of Regulation (EU, Euratom) 2024/2509 and Article 14(1) point (b) of Regulation (EU) 2021/522, the starting date of actions may be set, where appropriate, prior to signature of the grant agreement and costs may be eligible before submission of the proposal. This may be needed because, ERN grants are continuous grants that support the ERN infrastructure, with ongoing tasks and deliverables that cannot be interrupted.

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

OBJECTIVES, SCOPE AND ACTIVITIES

¹¹⁵ [European Reference Networks - Public Health - European Commission.](#)

¹¹⁶ OJ L 88, 4.04.2011, ELI: <http://data.europa.eu/eli/dir/2011/24/oj>. Consolidated text: ELI: <http://data.europa.eu/eli/dir/2011/24/2025-01-12>.

The proposed action will support coordinating centres and members of the 24 ERNs for the coordination, management and operational activities. The action aims to fulfil the goals of the network including, through:

- coordination, management and operational activities of ERNs;
- collaboration with patients' organisations, empowering patients by leveraging their expertise and experiences;
- knowledge generation and exchanges of best practice concerning diagnosis and the delivery of high-quality and cost-effective healthcare for patients with rare or low prevalence diseases;
- evidence generation regarding the efficiency of genomic data-driven approaches to diagnosing rare disease patients and their integration into regular healthcare delivery, including cross-border healthcare;
- raising awareness and dissemination of generated knowledge on rare or low prevalence diseases to health practitioners in the Member States;
- coordination of and support for development and updating of clinical practice guidelines and other clinical decision support tools;
- coordination, promotion, and management of professional training and educational activities, including through the ERN virtual academy;
- coordination, promotion, management and support for virtual discussions on clinical cases through the Clinical Patient Management System IT tool, including contribution to its development;
- coordination of and support for functioning of ERN registries, including joining of the European Platform on Rare Disease Registration (EU RD Platform)¹¹⁷ in line with their technical specifications and coordination and support for data management, taking into consideration the European Health Data Space (EHDS) and the data infrastructure established under the 1+ Million Genomes initiative, as well as research readiness activities and coordination activities;
- coordination, management and support activities for long-term sustainability of the ERN system and better integration of ERNs into national systems;
- support to collaboration activities to effectively link Ukrainian competent authorities and healthcare units to the ERNs, contributing to capacity building and best practice sharing with Ukraine, building on the experience of the Rare Diseases Hub Ukraine.

EXPECTED RESULTS AND IMPACT

This action will ensure continuity for ERNs' coordination and operation for the period 2027-2029 and will support the provision of specialised healthcare for rare diseases, development of new guidelines, build evidence of best practices, develop educational programmes and training, contributing to set the research agenda in collaboration with stakeholders including patient representatives, and share knowledge through participation in virtual multidisciplinary teams. It will also support the use of the IT tool for virtual discussions of clinical cases, its adaptation to specific needs of ERNs and the functioning of ERNs registries.

In addition, the action will support ERNs towards their integration into national health systems and future sustainability. This action will help in pooling knowledge, expertise and resources for the benefit of patients suffering from rare diseases in the Union and related health professionals, including by promoting common standards and tools, allowing for better sharing

¹¹⁷ [European Platform on Rare Disease Registration | European Platform on Rare Disease Registration.](#)

and interoperability of (anonymised) rare disease patients' data through the EU RD Platform, as an opportunity for research projects Moreover, synergetic opportunities offered by the 1+Million Genomes initiative and its implementing projects under the Digital Europe Programme should be leveraged in view of additional data available to support personalised healthcare provision, research activities and public health policymaking. The action will also support capacity building and best practice sharing with Ukraine.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – DP-g-26-11	Q4/2026	EUR 40 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to designated ERNs (set out in accordance with Union law referred to in Article 13(6) of Regulation (EU) 2021/522) in accordance with Article 198(1), point (d), of Regulation (EU, Euratom) 2024/2509	HaDEA	Coordinating centres and members of the network of the 24 established ERNs

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

3.1. CANCER INITIATIVES

CR/CV&NCD-g-26-12 European guidelines and quality assurance scheme for gastric cancer (DG SANTE)

POLICY CONTEXT

The Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC¹¹⁸ was adopted on 9 December 2022. The new Council Recommendation is part of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan.

In addition to the cancer screening programmes for breast, colorectal and cervical as recommended under the 2003 Council Recommendation, the new Recommendation suggests screening for lung, prostate, and under certain conditions, gastric cancer, specifically in those countries with the highest gastric cancer incidence and death rates.

Through the Commission Initiatives on Breast and Colorectal Cancer, a system and streamlined methodology for the development of the European guidelines for cancer prevention, screening, and diagnosis and for the European quality assurance scheme covering the entire care pathway has been developed. Based on this existing methodology, guidelines for the screening of the other five cancer sites will be developed as indicated in the Recommendation. While work on breast and colorectal, as well as lung and prostate cancer are covered through activities funded under EU4Health Work Programmes 2023 and 2024, subsequent funding will be needed to continue the work done on cervical and gastric cancer. The initiatives on cervical and gastric cancer have been established through prior direct grants to the International Agency for Research on Cancer (EU4Health Work Programmes 2022 and 2024).

The award of a direct grant to WHO's specialised Agency for Research on Cancer ('IARC') as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified. This action can best be carried out by IARC as it has the required, unique expertise and capacity to inform and guide the development of public health policies for the development of gastric cancer guidelines and quality assurance schemes. IARC is trained in the specific methodology required to develop the guidelines and quality assurance scheme under the umbrella of the Commission Initiatives. Additionally, IARC is leading the currently ongoing EU-GAINS¹¹⁹ project, which serves to establish the Commission Initiative on Gastric Cancer, and is therefore responsible to develop the groundwork this new action will build on. In addition, being an international public organisation, IARC can ensure that the work will be carried out with the required independence from vested interest.

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

¹¹⁸ [Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC \(OJ C 473, 13.12.2022, p. 1\).](#)

¹¹⁹ [EU-GAINS project.](#)

diseases (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of the action is to continue with the development of the European guidelines and quality assurance scheme for gastric cancer prevention, and preparatory work for gastric cancer screening, as part of the European Commission Initiative on Gastric Cancer¹²⁰. The ongoing project EU-GAINS¹²¹, which this action will build on, covers the first step of the care pathway, focussing on prevention, and lays the groundwork for the development of the quality assurance scheme. The action will continue the work on gastric cancer prevention and start developing the quality assurance scheme.

The action will include the following activities:

- expansion of the European Commission Initiative on a Gastric Cancer Working Group (expert panel) as needed;
- further development of the European Gastric Cancer Guidelines with recommendations, covering primary prevention, potential screening and diagnostic approaches (identify the population or subgroups of the population that may benefit from such approaches), and associated quality indicators to monitor the implementation of the respective recommendations;
- development of requirements for the European Quality Assurance (QA) Scheme for H. pylori screen-and-treat services following the recommendations..

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

- selection of additional healthcare questions for the guideline development related to gastric cancer prevention, following the prioritisation by the working group;
- review of existing guidelines covering screening approaches for gastric cancer early detection;
- publication on the JRC web-hub of evidence-based guidelines and their recommendations based on the GRADE Evidence to Decision Framework and informed by systematic reviews of the evidence;
- development, evaluation, rating and definition of requirements and indicators according to established criteria and methodologies and informed by systematic reviews of the evidence.
- feasibility assessment of the developed requirements for inclusion in the European QA Scheme manual for gastric cancer care services.

The approach will follow the methodology adopted under the EC Initiatives on Cancer Screening and Care (European Commission Initiative on Breast Cancer, European Commission Initiative on Colorectal Cancer, and others) overseen by the Commission's Joint Research Centre.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

¹²⁰ [European Commission Initiative on Gastric Cancer | Cancer Screening, Diagnosis and Care.](#)
¹²¹ [IARC hosts EU-GAINS kick-off meeting – IARC.](#)

- collection of requirements and/or quality indicators for the European Quality Assurance Scheme for H. pylori screen-and-treat services.
- up-to-date European gastric cancer guidelines with additional recommendations on gastric cancer prevention (including screen-and-treat approach for *helicobacter pylori*) screening and diagnosis; published on the JRC web-hub.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants- CR/CV&NCD -g-26-12	Q4/2026	EUR 900 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant for activities with specific characteristics that require a particular type of body on account of its technical competence in accordance with Article 198(1), point (f), of Regulation (EU, Euratom) 2024/2509	HaDEA	International Agency for Research on Cancer (IARC)

CR/CV&NCD-g-26-13 Call for proposals to support dissemination and evaluating the awareness level of the 5th edition of the European Code Against Cancer (DG SANTE)

POLICY CONTEXT

The Europe's Beating Cancer Plan aims to reduce the burden of cancer through prevention and improved health literacy, recognizing that approximately 40% of cancer cases in the EU can be prevented. By enhancing health literacy and providing accessible, understandable information on cancer prevention, the Plan seeks to reduce cancer-related disparities and promote a healthier population.

The European Code Against Cancer, first launched in 1987, provides evidence-based recommendations to help individuals reduce their risk of developing cancer. The 5th edition of the Code¹²² has been updated to reflect the latest scientific evidence. The dissemination of the 5th edition of the Code is crucial to ensure that the latest scientific evidence is translated into action and that the public is aware of the steps they can take to reduce their risk of cancer. Improving knowledge of cancer risk factors among the most disadvantaged populations is important for reducing inequalities.

An EU Mobile App for Cancer Prevention has been developed as a tool to disseminate the Code's recommendations.

¹²² [European Code Against Cancer | 14 ways to prevent cancer.](#)

Many of the major risk factors for cancer are also risk factors for other non-communicable diseases (NCDs), such as cardiovascular health. The aforementioned actions thereby support a comprehensive approach to health promotion and prevention in line with the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare.

There are also opportunities for synergies with corresponding prevention activities of the EU Cancer Mission¹²³.

This action supports the implementation of the Europe's Beating Cancer Plan flagship initiative and objective 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 objective defined in Article 4, point (a), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this call is to support the dissemination of the 5th edition of the European Code Against Cancer to the general public, healthcare professionals, and other stakeholders to achieve the goal to make at least 80% of the population aware of the Code.

The specific objectives and activities of this call are to:

- raise awareness of the European Code Against Cancer among the general public, including a social media campaign, to reach a wide audience but also focus on vulnerable and disadvantaged populations, and encourage the integration of the Code's recommendations into daily life, fostering healthy lifestyle choices;
- develop, promote and/or use educational materials (such as brochures, infographics, videos) to support the dissemination of the European Code Against Cancer and promote its adoption among the target audience;
- put into use the 'EU Mobile App for Cancer Prevention' (hosted on Azure) for dissemination of the European Code Against Cancer by putting it into production, hosting it, improving, maintaining, and disseminating it to the target audience, thereby ensuring its usability, technical functionality, and promotion among the general population;
- evaluate the level of awareness of the Code in the EU population, with the view of making at least 80% of the population aware of the Code.

Synergies with other relevant initiatives, such as the EU Cardiovascular Health Plan – the Safe Hearts Plan can be explored.

EXPECTED RESULTS AND IMPACT

The expected results and impact of this call include:

- increased awareness of the 5th edition of the European Code Against Cancer among the general public, healthcare professionals, and other stakeholders, with a focus on reducing inequalities in health literacy.
- development and implementation of effective dissemination strategies and contributing to a significant increase in awareness and adoption of the Code's recommendations.
- in the mid-term, contribution to the achievement of the Europe's Beating Cancer Plan's objective of making 80% of the population aware of the Code.

¹²³

[Cancer mission objectives - Research and innovation - European Commission.](#)

- in the long-term, a reduction in cancer incidence, as well as improved health outcomes for individuals at high risk of developing cancer, through the promotion of healthy lifestyle choices and the adoption of the Code's recommendations.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – CR/CV&NCD -g-26-13	Q4/2026	EUR 3 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Public health authorities, international organisations, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, civil society organisations: associations, foundations, NGOs, enterprises, private entities, social media, press and journalist associations

CR/CV&NCD-g-26-14 Call for proposals to support the continued implementation and sustainability of the inter-specialty cancer training programme (DG SANTE)

POLICY CONTEXT

Europe's Beating Cancer Plan, under the objective of ensuring high standards of care, recognises that high-quality cancer care depends on a well-trained and continuously supported workforce. To achieve this, the Plan commits to strengthening the cancer workforce through an inter-specialty cancer training programme.

Traditionally, disciplines such as medical, surgical, and radiation oncology, pathology, and palliative care, are often trained in isolation. This siloed approach leads to fragmented care and ultimately poorer outcomes for patients. Inter-specialty oncology training addresses these gaps by fostering collaboration, upskilling healthcare professionals, and reducing regional disparities in access to high-quality cancer services.

The inter-specialty cancer training programme developed in previous projects (INTERACT-EUROPE¹²⁴ and INTERACT-EUROPE 100¹²⁵) aims to ensure that oncologists, surgeons, radiologists, oncology nurses and related specialists can update their skills throughout their

¹²⁴ [INTERACT-EUROPE - Public Health - European Commission.](#)

¹²⁵ [INTERACT-EUROPE 100 - Public Health - European Commission.](#)

professional lives, including in situations where exceptional conditions may jeopardise the delivery of treatment and care. The programme consists of five courses (leadership, professional practice and scholarship, communication and collaboration, clinical expertise, health advocacy and survivorship) representing the expertise of different medical specialties involved in oncology care, and two add-on units (paediatric oncology and displaced persons).

The next challenge is to implement the programme in further cancer centres and ensure the sustainability of the programme. A follow up project will expand access in underserved regions where cancer care disparities remain, as well as to ensure that the skills and knowledge built during INTERACT-EUROPE 100 do not stop and a pathway for its sustainability is implemented.

By promoting cross-border training and information exchange, this action strengthens EU cancer centres and contributes to the implementation of the Cancer Plan's objective to ensure a high-quality cancer workforce and implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522. It also supports the Draghi Report on the future of European competitiveness¹²⁶ priorities of investing in workforce upskilling and increasing cohesion across Europe.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this call is to scale up the implementation of the inter-specialty cancer training programme in EU cancer centres and ensure its long-term impact through the development and implementation of sustainability activities.

The specific activities will include:

- Recruitment of 50 additional cancer centres beyond those that participated in the INTERACT-EUROPE 100 training programme, across at least 20 Member States and EU4Health associated countries, with a focus on remote areas, ultraperipheral EU regions, and those where cancer care disparities remain highest. Additional trainers and trainees should also be recruited from centres already involved in the previous project INTERACT-EUROPE 100, in order to maximise the number of healthcare professionals benefiting from the training in each centre.
- Implementation of the inter-specialty cancer training programme in these cancer centres. The training will be based on the curriculum developed in INTERACT-EUROPE and finalised in INTERACT-EUROPE 100, leveraging a combination of in-person events and a multilingual online platform, updated following participant feedback as part of the evaluation in the previous project. The programme is expected to train the cancer workforce from all the medical specialties involved in cancer care.
- Collaboration and ensuring full synergy with existing EU cancer actions, i.e. Networks of Expertise on cancer to disseminate the training programme, and the EU Network of Comprehensive Cancer Centres where the training programme can be rolled out.
- Building on results from EU4Health projects on professional education developing digital skills of oncologists, e.g. Transition, DigiCanTrain and explore synergies with the actions funded under [Advanced Digital Skills \(DIGITAL-2026-SKILLS-10\)](#) topic.

¹²⁶ [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](#).

- Equity and inclusion dimension: prioritisation of cancer centres from regions with limited resources, as well as ensuring a gender balance in participants.
- Implementation of the sustainability recommendations of the Sustainability and Exploitation Plan from the previous project, to ensure that the benefits of the programme continue beyond the project's life cycle. This may involve a sustainability roadmap.

EXPECTED RESULTS AND IMPACT

In the short term, the project will expand the programme to 50 additional cancer centres from 20+ Member States and third countries associated to the EU4Health programme, including remote, ultraperipheral, and underserved regions. This will increase the number of trainers and trainees with inter-specialty skills, strengthening collaboration between oncologists, surgeons, radiologists, pathologists, nurses, and palliative care professionals, among others, in multi-professional teams. A multilingual digital learning platform will ensure that training is inclusive and aligned with workforce needs.

In the mid-term, the action will contribute to a more skilled cancer workforce. Equity gaps will be reduced by including centres from resource-limited regions and ensuring gender balance in participation. The Train-the-Trainer model will ensure knowledge transfer by equipping trainers to implement the programme in their local hospitals. The strong focus on sustainability will ensure that results are long lasting.

The action will strengthen implementation of the Cancer Plan. The expected result is a real improvement in the quality of multidisciplinary team meetings in cancer centres. Although the call's focus is on healthcare professionals, its end goal is to improve the quality of care. Digital tools will allow for scalable and accessible training, with flexibility to reach less-resourced hospitals. This is particularly impactful where physical training opportunities may be limited or hard to access.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – CR/CV&NCD -g-26-14	Q4/2026	EUR 2 440 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Public health authorities, international organisations, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, expert networks, incl. ERNs, established networks in the field of public health, civil

		society organisations, associations, foundations, NGOs
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3.2. CARDIOVASCULAR HEALTH

CR/CV&NCD-g-26-15 Call for proposals to support an EU flagship programme on cardiovascular diseases: a multidisciplinary and patient-centred approach to prevention, early detection, treatment and care (DG SANTE)

POLICY CONTEXT

In the Union, 1.7 million lives are lost every year because of cardiovascular diseases, which are the leading cause of death in the EU¹²⁷. They are also a significant cause of disability, premature retirement, and absenteeism, negatively impacting quality of life, shortening life expectancy and contributing to decreased productivity and economic output, costing the Union around EUR 282 billion annually¹²⁸.

Projections indicate a significant increase in cardiovascular disease prevalence and mortality by 2050, mainly due to the ageing population and other societal trends. Given this increasing impact of cardiovascular diseases on health systems and on individuals, a comprehensive and coordinated EU cardiovascular health plan: the Safe Hearts Plan¹²⁹ with impactful actions that have EU-added value could bring significant benefits.

President von der Leyen's political guidelines¹³⁰ and her mission letter¹³¹ to the Commissioner for Health and Animal Welfare call for the Commission to step up its work on preventive health, particularly for cardiovascular diseases. This echoes the firm recognition and call for action to tackle this public health challenge by the Council of the European Union¹³², the European Parliament¹³³ and stakeholders.

Building on ongoing actions under the 'Healthier together' initiative funded under the EU4Health Programme¹³⁴, and on relevant research and innovation actions funded under Horizon Europe¹³⁵ this action contributes to the EU cardiovascular health plan: the Safe Hearts Plan which aims to improve public health at both individual and societal level and to contribute to competitiveness and innovation, improving EU citizens' quality of life. The plan includes three key action areas with the most potential for EU-added value: prevention, early detection and screening, and management, care and rehabilitation. It also addresses the three horizontal themes of research and innovation, data and digitalisation, and health inequalities.

While prevention is key to reducing cardiovascular diseases, ensuring access to high-quality, coordinated, and patient-centred care is essential, especially for people living with multiple chronic conditions. Personalised treatment and care can improve quality of life and reduce costs, yet inequalities in access to effective care exist across Member States. Women face

¹²⁷ [Health at a Glance: Europe 2024 | OECD](#).

¹²⁸ [Full Report: The State of Cardiovascular Health in the European Union | OECD](#).

¹²⁹ [Cardiovascular health - Public Health - European Commission](#).

¹³⁰ [Political guidelines for the next European Commission 2024–2029](#).

¹³¹ [Mission letter to the Commissioner for Health and Animal Welfare](#).

¹³² In December 2024 the Council adopted Council Conclusions on the improvement of cardiovascular health in the European Union: <https://data.consilium.europa.eu/doc/document/ST-15315-2024-INIT/en/pdf>.

¹³³ [MEP Heart Group - The Members of the European Parliament Heart Group](#).

¹³⁴ The joint actions [JACARDI](#) and [PreventNCD](#), and stakeholder-led projects.

¹³⁵ The European Partnership on transforming health and care systems (THCS) [JTC 2026 - Access to CareEP](#) [PerMed Joint Transnational Call \(JTC\) 2026 - European Partnership for Personalised Medicine - EP PerMed](#) Joint Transnational Calls of 2026, and the call HORIZON-HLTH-2026-01-DISEASE-11: Understanding of sex and/or gender-specific mechanisms of cardiovascular diseases: determinants, risk factors and pathways.

significant challenges in diagnosis and treatment, which calls for more awareness in care delivery. Moreover, digital tools can empower patients, enhance self-management, and improve care continuity, particularly in underserved areas. Therefore, supporting person-centred digital care models through EU guidance, and creating a European network of expertise would support better diagnosis, treatment, rehabilitation, and long-term management.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The proposed action addresses the need to reduce the burden of cardiovascular diseases across the EU through a multidisciplinary and patient-centred approach to prevention, early detection, treatment and care.

This action aims to support capacity building at national level through collaboration among national authorities and stakeholders to address the burden from cardiovascular diseases, including through innovative, personalised and digital solutions. The aim is to support the development and piloting of an EU guidance on personalised, digitally enabled treatment and monitoring of cardiovascular diseases.

The action will support the implementation of the EU cardiovascular health plan: the Safe Hearts Plan with a focus on enhancing care pathways, improving health literacy, and empowering patients, especially those in vulnerable groups and underserved areas, to take an active role in managing their health, including through digital solutions. It will support Member States in implementing the EU cardiovascular health plan – the Safe Hearts Plan with a coordinated approach for cardiovascular diseases treatment and care, integrating digital solutions to enable personalised, patient-centred solutions building on and taking into account the results of the EU4Health 2025 work programme flagship on cardiovascular health and data/AI. The action will support the creation of a network of expertise with academia, health professionals and patient associations.

Actions should be co-designed with a multidisciplinary approach, and include expertise from the academia, health professionals' guidance, and patients' lived experience.

Specific objectives:

- a) to support Member States in building their capacities to prevent and manage cardiovascular diseases;
- b) to support Member States in implementing the EU cardiovascular health plan: the Safe Hearts Plan with a coordinated approach for cardiovascular diseases treatment and care, integrating digital solutions to enable personalised, patient-centred solutions building on and taking into account the results of the EU4Health 2025 work programme flagship on cardiovascular health and data/AI;
- c) to create a network of expertise with academia, health professionals and patient associations;
- d) to empower patients, and improve health literacy in particular among vulnerable groups, such as children, young people, women and socio-economically disadvantaged groups.

Deliverables:

- a) creation of a European network of expertise linking comprehensive cardiovascular health centres in the Union, to facilitate the uptake of diagnosis and treatment, as well

as rehabilitation and long-term care and effective management, including adherence to medicines and medical advice;

- b) development of EU guidance on cardiovascular health treatment with digitally personalised integrated patient pathways;
- c) design and implementation of health literacy actions to enable patients to manage their own health;
- d) development and provision of a multidisciplinary training programme for health professionals to facilitate the integration of the EU cardiovascular health plan: the Safe Hearts Plan, including the EU guidance on personalised treatment and monitoring of cardiovascular diseases to daily practice;
- e) development of guidance on improving uptake of innovative care models to support rehabilitation from cardiovascular diseases and related comorbidities;
- f) development of a comprehensive food processing assessment system to provide consumers with science-based information on food processing, in order to encourage shifts towards healthier diets.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- The European network of expertise linking cardiovascular health centres will enable standardised collaboration across the EU, improving the consistency and quality of cardiovascular care. It will enhance patient outcomes through streamlined diagnosis, treatment, rehabilitation, and long-term management;
- The EU guidance on digitally personalised integrated patient pathways will promote tailored treatment plans leveraging digital tools, ensuring more precise and effective cardiovascular care. This approach will improve patient adherence and health outcomes across diverse populations;
- The health literacy actions for patient self-management will empower patients with the knowledge and skills to actively manage their cardiovascular health, leading to increased engagement and better disease control. Improved health literacy will reduce complications and healthcare costs;
- The multidisciplinary training programme for health professionals will equip healthcare providers with the latest knowledge and skills to implement the EU cardiovascular health plan: the Safe Hearts Plan effectively. This will foster integrated, patient-centred care and enhance clinical practice consistency across member states;
- The guidance on uptake of innovative care models for rehabilitation will support the adoption of novel rehabilitation approaches that address cardiovascular disease and comorbidities. It will improve recovery rates, quality of life, and reduce hospital readmissions;
- A European tool to assess the health impact of ultra processed food and to empower patients to make the healthy choice in their diets.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
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Call for Proposals – CR/CV&NCD-g-26-15	Q4/2026	EUR 20 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States' authorities (Public health authorities), academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, expert networks, civil society organisations, private entities (for profit/not for profit).

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

4.1. PRIMARY CARE AND HEALTH WORKFORCE

HS-g-26-16 Call for proposals to facilitate the use of emerging AI tools in primary care and the required health workforce skills (DG SANTE)

Policy context

Primary care is crucial in supporting population health and addressing health crises. Robust primary care is a crucial component in health system reforms aimed at enhancing accessibility, effectiveness, and sustainability. This is particularly important in an era of increasing healthcare demand due to the rising prevalence of non-communicable diseases. Yet, most Member States experience shortages of health workers in primary care, limiting its capacity to respond to population needs.

Artificial intelligence (AI) has emerged as a pivotal means for transforming healthcare, including primary care. By streamlining documentation, aiding in diagnosis and clinical decision-making, automating routine tasks, and predicting patient needs, AI can bolster the efforts of health professionals and enhance patient outcomes. The current digital evolution provides an opportunity to support integrated care, interdisciplinary collaboration of health professionals and adapt to changing regulatory frameworks such as Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space¹³⁶ (EHDS). The EHDS supports stronger primary care by enhancing the digital skills of health professionals and the digital literacy of patients, enabling more data-driven, efficient, and patient-centred care.

Leveraging the potential of AI to enhance the productivity of the health workforce and optimise the use of their skills is crucial to safeguarding and bolstering the role of primary care in health promotion and in prevention and management of non-communicable diseases. Despite its promising potential, the deployment of AI in primary care remains limited. There is a need for deployment-specific strategies tailored to the unique characteristics and challenges of primary care settings. This complements the work undertaken by the Apply AI Strategy¹³⁷.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action seeks to foster the meaningful use of AI tools in primary care and explore their implications on skills for healthcare providers. It focuses on strategies for AI integration in daily practice, optimising workflows and supporting health professionals in adapting their skills and competences in response to AI use. Emphasis is placed on applications of AI for preventing and managing non-communicable diseases that represent significant health burdens (such as cancer, cardiovascular diseases, chronic respiratory diseases, diabetes and mental health), as well as for other areas related to public health aspects of primary care.

¹³⁶ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

¹³⁷ [Apply AI Strategy](#).

Consortia should include health professionals, public authorities or regulators (such as managers of primary care facilities, health or other public authorities), AI users (such as primary care providers, medical and patient organisations) and AI developers (academia, IT specialists or industry; to make their solutions available to pilot them and collect additional evidence, in view of refining and adapting existing AI tools to improve efficacy and user experience).

One project is expected to be funded under this call.

Activities shall not concern any AI technology development, but rather focus on:

- a) Analysis and identification of barriers and enabling factors for successful deployment of AI specifically in primary care, building on the Commission study on AI deployment¹³⁸.
- b) Developing implementation strategies to guide the uptake of AI in primary care.
 - Deployment-specific strategies tailored to the unique characteristics and challenges of primary care settings, building on the deployment practices identified by COMPASS-AI¹³⁹. The strategies should include effective mechanisms to adapt workflows and fit with local clinical guidelines and protocols.
 - The strategies could outline key elements such as successful stepwise approaches with milestones, stakeholder roles, barriers and enablers across the innovation-to-adoption pathway. Specific attention should go to tackling training and support needs, overcoming change management barriers, and ensuring interoperability with other digital health tools such as Electronic Health Records. The aim is to guide the safe, effective, equitable and inclusive adoption of AI solutions.
 - Strategies should target health authorities and primary care providers and be tailored to their needs and the needs of patients. The strategies should target the specific context of the regions or Member States which participate in the project consortium, and should also include aspects that are applicable to the wider health community.
- c) Selecting, piloting and evaluating promising applications of AI in primary care settings that are adaptable to the target population and local needs. Both emerging and more established AI tools are in scope. Tools can include, for example, those used for streamlining documentation with scribes, aiding in diagnosis and clinical decision-making, automating routine tasks, and predicting patient needs. For the more established tools, activities can include the transfer of good practices which embed such AI tools, from health authorities or healthcare providers that have pioneered their use in primary care to other health authorities or healthcare providers that seek to apply them for the first time in synergy with the activities undertaken under the Apply AI strategy.
- d) Providing evidence to demonstrate benefits from the use of various types of AI tools in primary care in terms of efficient use of resources, supporting health workers to meet the needs of patient populations, or potential benefits in improved health outcomes from more effective prevention and management of non-communicable diseases. Pertinent emerging risks and drawbacks identified should also be described.
- e) Building learning communities, to facilitate the exchange of knowledge, good practices, and lessons learnt; to support capacity building; and to enhance innovation in primary

¹³⁸ European Commission: Directorate-General for Health and Food Safety, EEIG, Open Evidence and PwC, *Study on the deployment of AI in healthcare – Final report*, Publications Office of the European Union, 2025, <https://data.europa.eu/doi/10.2875/2169577>.

¹³⁹ [Compass-AI](#).

care settings, in synergy with the activities under the Apply AI strategy, in particular the European network of AI-powered advanced screening centres. Activities could include:

- Keeping primary care practitioners abreast of new AI tools and their application in primary care.
- Bringing together AI developers, users (health professionals and patients) and regulators to strengthen the alignment between needs and innovation, support co-creation and continuous feedback loops.
- Engaging with authorities and primary care practitioners to expand the learning community and share results in relevant fora.
- Educating and empowering primary care practitioners by facilitating participation in existing relevant continuous professional trainings. Key topics could include:
 - Technical training: Providing foundational education on AI literacy and data management.
 - Clinical integration: Offering guidance on optimising workflows with AI tools.
 - Ethical and regulatory considerations: Addressing the ethical use of AI and compliance with relevant regulations.
 - Soft skills development: Enhancing skills in patient communication, interdisciplinary collaboration, and change management
- Key methods could include workshops and webinars with innovators and pioneers in the use of AI tools, peer learning sessions, train the trainer programmes, resources repository, and exchange visits.
- Developing working relations with the COMPASS-AI project, and make use and build upon the results of several Union funded projects that strengthen digital skills for health professionals and promote the use of digital tools and AI in health service delivery¹⁴⁰.

Mandatory deliverables:

- a) Analysis report: A report identifying barriers and success factors in the deployment of AI in primary care, supported by case studies, targeted interviews and data, building on the Commission study on AI deployment¹⁴¹. This should include evidence on the impact of AI on resource efficiency, support to healthcare workers, and enhanced health outcomes in primary care, especially in the context of non-communicable diseases.
- b) Implementation strategies for AI adoption in primary care settings, including workflow adaptation and integration of clinical guidelines. These may also include guidelines or toolboxes for transferring and implementing established AI practices from experienced to new adopters, supported by learning community exchanges.
- c) Policy briefs summarising core implementation strategies adaptable to regional contexts, and distilling widely applicable elements which can be used by stakeholders beyond the project consortium.
- d) Pilot evaluation reports: Documentation of pilot studies, including evaluation of pilot outcomes with qualitative and quantitative indicators, and scalability analyses for the piloted AI tools in primary care.

¹⁴⁰

Projects listed under the [EU Funding & Tenders Portal](#), as well as projects [Transforming Health and Care Systems \(THCS\) partnership](#), [BeWell](#), [DS4Health](#), [AI and Health](#), [ManagiDITH](#), [BioNT](#), [SUSA](#).

- e) Learning community reports: Overview of scheduled and conducted educational events and activities featuring AI innovators and pioneers in the use of AI in primary care, promoting knowledge exchange and skill development.

EXPECTED RESULTS AND IMPACT

This action is expected to:

- a) Strengthen the evidence for improved policy making on AI deployment in primary care, including through indicators for evaluating AI-supported practices in primary care.
- b) Create actionable, context-specific implementation strategies that facilitate the safe, equitable and effective adoption of AI solutions designed to meet the unique needs of primary care environments.
- c) Successfully transfer and implement selected AI tools across different European contexts demonstrating enhanced productivity, clinical decision-making, and patient outcomes in primary care.
- d) Foster a vibrant network of practitioners, developers, and regulators actively exchanging on innovative AI tools and insights on their use in primary care, fostering a culture of continuous learning and adaptation, through sharing of lessons learnt in implementing and using AI tools in daily practice.
- e) Equip primary care practitioners with the latest skills and knowledge in AI tools and their applications, leading to more confident and skilled use of AI technology in primary care practice.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – HS-g-26-16	Q4/2026	EUR 2 500 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States' authorities, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, NGOs, private entities (for profit/not for profit)

4.2. PHARMACEUTICAL LEGISLATION AND STRATEGY

HS-g-26-17 Direct grants to Member States' authorities to support capacity building and AI capabilities in the European medicines regulatory network, including implementation of innovative regulatory aspects of the new EU pharmaceutical legislation (DG SANTE)

POLICY CONTEXT

The European medicines regulatory network ('EMRN')¹⁴² is a closely coordinated regulatory network of national competent authorities ('NCAs') in the Member States of the European Economic Area ('EEA') working together with the European Medicines Agency ('EMA') and the Commission. It plays a vital role in ensuring that medicines available to patients across the Union are of high quality, safe, and effective. NCA experts perform scientific assessments and lead the evaluation process for medicine authorisation applications at national and Union level, often working in multidisciplinary teams from different countries, to ensure the best possible expertise is applied to each evaluation.

The pharmaceutical regulatory environment has become increasingly complex, dynamic and global, driven by rapid scientific advancements, evolving patient needs, and the need to protect public health. The increasing volume and complexity of regulatory procedures, coupled with the accelerated pace of scientific advancements, has put significant pressure on the capacity of NCAs and the EMA.

In addition, the forthcoming implementation of the new Union pharmaceutical legislation marks a significant transformation of the regulatory framework. It brings forward ambitious goals to foster innovation, digitisation, real-world data integration, improve access to medicines, enhance transparency, and reinforce patient-centricity. It likewise seeks to make medicines more environmentally sustainable, notably through strengthened environmental risk assessment requirements, drawing new scientific disciplines into the regulatory remit and reinforcing the case for sustained investment in the network's capacity. This evolving legal landscape imposes new responsibilities on regulators and assessors, requiring them to adapt rapidly to emerging scientific, technological, and procedural demands, while adhering to competitive assessment timelines.

To maintain and strengthen their vital role in this environment and to ensure patient safety and timely access to innovative therapies, medicines regulators must focus on adaptability, continued development of scientific and operational capacity, increased reliance on data and technology like artificial intelligence (AI) or regulatory intelligence, and fostering collaboration among the EMRN.

In this context, strengthening the knowledge, skills, and infrastructure of regulatory staff is not only a matter of operational necessity but a strategic imperative to ensure the EMRN's resilience, efficiency, and excellence.

Additionally, the rapid advancement of AI has created both opportunities and disparities in its development and use among NCAs. Currently, there is significant variability in the awareness, maturity, and implementation of AI-based tools and methods across agencies. This fragmented approach highlights an urgent need for enhanced collaboration, structured knowledge exchange, and harmonised development of AI tools.

¹⁴² [European medicines regulatory network](#).

These developments underscore the continued need to invest in targeted capacity building across the EMRN.

The policy objective of this project is therefore aligned with broader Union goals, including the European Health Union¹⁴³, the Digital Europe Programme¹⁴⁴, the Pharmaceutical Strategy for Europe¹⁴⁵, the Commission's proposal for a European Biotech Act¹⁴⁶, and the European medicines agencies network strategy 2028¹⁴⁷ all of which emphasise the need for a robust, adaptive, and forward-looking regulatory system capable of responding to public health challenges while supporting scientific progress and competitiveness in the pharmaceutical sector.

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 Europe¹⁴⁸ 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 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), (f) and (h), 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), point (a)(iii), of the STEP Regulation and meets the condition under Article 2(2), point (b).

The action should synergise, where possible, with EU funded research and innovation in regulatory sciences such as projects funded under call topic HORIZON-HLTH-2026-01-IND-03: Regulatory science to support translational development of patient-centred health technologies and call topic [HORIZON-JU-IHI-2024-08-03-two-stage - Modelling regulatory sandbox mechanisms and enabling their deployment to support breakthrough innovation](#).

The Union's pharmaceutical legislation applies to all EEA countries, and they are part of the EMRN since the Union acquis on medicinal products has EEA relevance and has been incorporated into the EEA Agreement. Therefore, besides the EU Member States, there is a necessity to involve also Norway, Iceland and Liechtenstein in this joint action with the aim of harmonising implementation of the Union pharmaceutical acquis. In consequence, as an EEA country without association to the EU4Health Programme, Liechtenstein authorities are eligible to participate in the project as associated partner without funding in accordance with Article 13(1), point (a)(iii), (2) and (3) of Regulation (EU) 2021/522.

¹⁴³ [European Health Union](#).

¹⁴⁴ [The Digital Europe Programme](#).

¹⁴⁵ 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](#).

¹⁴⁶ [European Biotech Act - Public Health - European Commission](#).

¹⁴⁷ [European medicines agencies network strategy](#).

¹⁴⁸ Pharmaceutical Strategy for Europe ([COM\(2020\) 761 final](#)).

With respect to other associated third countries to the EU4Health Programme: this joint action will work with information of a commercially confidential nature in line with the Directive 2001/83/EC and Regulation (EC) No 726/2004, namely regulatory files, assessment reports and other materials derived from them. Therefore, NCAs from those countries that do not have the right to access these materials, based on clearance received independently from EMA for participation in centralised procedures, or access to EU-NTC can only partially participate in this joint action's related activities.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this joint action is to support and strengthen further the EMRN's capacity and competence to adapt rapidly to emerging scientific and technological advancements and to regulatory innovation, by building on initiatives such as the IncreaseNET¹⁴⁹ project and the work of the Strategic Regulatory Optimisation Group¹⁵⁰ and by creating a framework for implementation of several additional activities, in particular the following:

- a) Supporting NCAs/EMRN during the significant transformation of the regulatory framework established by the new pharmaceutical legislation, in particular in areas such as:
 - investigation on possible sandbox frameworks;
 - adaptive pathways to provide earlier and ongoing access for patients to new medicines by allowing for flexible development and data generation;
 - Active Substance Master File certification;
 - expanding multinational assessment teams to cover innovation dossiers;
 - environmental risk assessment.
- b) Expanding the use of AI tools in IncreaseNET:
 - continue developing AI capabilities and knowledge-sharing in the EMRN;
 - continue deploying AI tools under a harmonised framework;
 - support processing of big data analytics and raw-data submissions.
- c) Supporting innovation:
 - support building a long-term collaboration mechanism with Academia and SMEs;
 - supporting scientific advice initiatives (SNSA¹⁵¹, PGRSA¹⁵², repurposing, framework for scientific advice to non-commercial sponsors);
 - support establishing innovation offices at NCAs;
 - intense collaboration with the European Innovation Network (EU-IN).
- d) Strengthening further the expertise and collaboration among the NCAs and within the EMRN:
 - support methodology assessment in areas such as clinical pharmacology, real-world evidence and data evaluation, pharmacogenomics, pharmacokinetics, (bio) statistics, and modelling and simulation.
- e) Closing gaps in national and EMRN scientific and operational capacity, including development and implementation of a common strategy for talent attraction, retention, and succession planning, to ensure the sustained availability of skilled assessors.
- f) Training development:

¹⁴⁹ [IncreaseNET](#).

¹⁵⁰ [Strategic Regulatory Optimisation Group](#).

¹⁵¹ [Simultaneous National Scientific Advice](#).

¹⁵² Pre-GRANT Regulatory Scientific Advice (still under development). Initial framework proposed during the STARS project [final report](#).

- develop and implement common EU regulatory curriculum frameworks¹⁵³ and related e-learning materials in high-interest areas, such as biologicals, biosimilars, advanced therapy medicinal products, combination products (such as medicinal products and medical devices), AI, innovation topics, new International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use¹⁵⁴ guidelines, methodology and pharmacometrics;
 - integrate learning materials across the EMRN into the EU Network Training Centre¹⁵⁵ (EU-NTC);
 - intense collaboration with EU-NTC.
- g) On-the-job training:
- continuation of the on-the-job training programme¹⁵⁶ developed under IncreaseNET, which provides practical, hands-on experience in real-world settings to strengthen NCA and EMRN's capabilities and overall effectiveness;
 - development of generic assessor profiles related to a common onboarding plan/strategy/framework.

A pilot to support capacity and competence building on cross-cutting topics for assessors is also proposed.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- a) Strengthened assessment capabilities and competences across the EMRN by providing structured training programmes and on-the-job learning opportunities;
- b) Increased harmonisation and efficiency across the NCAs through shared training initiatives, aligned processes, and enhanced cross-border cooperation;
- c) Promoted innovation in regulatory science, including the use of artificial intelligence and advanced data analytics tools, to ensure high-quality, efficient evidence assessment;
- d) A sustainable and well-structured regulatory workforce strategy established across the EMRN, addressing talent attraction, retention, and succession planning to safeguard the long-term availability of skilled assessors;
- e) Supported data-driven assessments and real-world evidence evaluation by investing digital capabilities and infrastructure;
- f) Strengthened collaboration mechanisms with academic institutions and industry to support regulatory excellence and innovation, to ensure assessors stay at the forefront of scientific, technological, and regulatory developments.

These expected results will build on the outcomes of the IncreaseNET project and the work of the Strategic Regulatory Optimisation Group, which have laid a strong foundation for workforce development, collaboration, and regulatory innovation. This would ensure that existing insights, tools, and recommendations are effectively integrated into future capacity-building and optimisation strategies. Additionally, these efforts will complement other EMA

¹⁵³ Currently developed curricula are available on the following link: [IncreaseNET – deliverables](#).

¹⁵⁴ [The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use](#).

¹⁵⁵ [The EU Network Training Centre](#).

¹⁵⁶ [EMA - Implementation of IncreaseNET On the Job Training Programme: Roles, responsibilities and process for involvement of Training Assessor, Shadow Assessor and iRapporteur /iCoRapporteur in Centralised procedures](#).

and EMRN initiatives, such as the European Network Training Centre (EU-NTC), European Innovation Network (EU-IN) and other EMA/HMA committees and working parties.

This will ensure that the EMRN remains equipped to deliver high-quality scientific assessments and continues to protect public health in an evolving regulatory environment.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Direct grants – HS-g-26-17	Q4/2026	EUR 7 900 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 198(1), point (c), of Regulation (EU, Euratom) 2024/2509	HaDEA	EU Member States' authorities, authorities of EEA countries associated to the EU4Health programme (Norway and Iceland) and other NCAs from third countries associated to the EU4Health programme according to their rights to access these materials, based on clearance received independently from EMA for participation in centralised procedures, or access to EU-NTC.

4.3. CRITICAL MEDICINES

HS-g-26-18 Call for proposals to support manufacturing capacity of critical medicinal products to strengthen the security of supply (DG SANTE)

POLICY CONTEXT

The Union faces increasing challenges with medicine shortages, posing significant risks to public health and patient care across Member States. In 2025, the Member States reported 58 medicines in shortage affecting the Union. Shortages are in particular problematic for critical medicines, where limited or no alternatives exist, and where insufficient supply may result in serious harm to patients.

In particular, shortages of medicines result from supply chain disruptions due to lack of diversification of key suppliers and vulnerabilities affecting the supply of key ingredients and components.

Global events such as the COVID-19 pandemic and recent geopolitical tensions have further exposed vulnerabilities in pharmaceutical supply chains. Shortages of critical medicines

threaten public health, disrupt healthcare systems and can reduce trust in healthcare across the Member States.

In response, the Commission has adopted a proposal for a Critical Medicines Act¹⁵⁷ (CMA) to strengthen the security of supply and the availability of critical medicinal products within the Union and improve the availability and accessibility of other medicinal products, where the market is not delivering.

One of the core measures of the proposed CMA is to facilitate investments in manufacturing capacity for critical medicines, their active substances and other key inputs in the Union. It aims to do so by the identification of strategic projects that create, increase or modernise the Union's manufacturing capacity for critical medicines or their ingredients. The Legislative Financial and Digital Statement accompanying the proposal includes the commitment of EUR 40 405 000 under the EU4Health in 2026.

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

In line with Article 136(3) of the Financial Regulation, this action may apply specific security and public order conditions to ensure the protection of critical medicines supply chains. These conditions may include restrictions on participation and requirements for manufacturing within the Union, in accordance with the CMA. The exact conditions will be determined in the call for proposals.

This action supports the policy priority to enhance the availability and security of supply of critical medicines in the Union, especially those with supply chain vulnerabilities. It implements the EU4Health Programme's general objective of improving the availability, accessibility, and affordability of medicinal 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 provide funding to strategic projects that create, increase or modernise the Union's manufacturing capacity for critical medicines included on the Union List of Critical Medicinal Products¹⁵⁸ and their active substances or key inputs, in particular projects that:

- (a) create or increase manufacturing capacity, including through new technologies and innovative manufacturing processes, for one or more critical medicinal products or for collecting or manufacturing their active substances;
- (b) modernise an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;
- (c) create or increase manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances; or
- (d) contribute to the roll-out in the Union of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.

¹⁵⁷ Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, [COM\(2025\) 102 final](#).

¹⁵⁸ [Union list of critical medicines](#).

This action seeks to mitigate vulnerabilities in supply chains of critical medicines by reinforcing manufacturing capacities in the Union and diversifying supply sources, thereby improving availability of critical medicines for patients in the Union. Therefore, this action will target in particular projects that improve resilience within the supply chains of critical medicines and address a vulnerability that may compromise the continuous supply of these medicinal products to patients in the Union, including due to the lack of supply chain diversification or due to a high level of dependency on countries outside the Union for the manufacturing of the critical medicinal products or their active substances or both.

The aim is to support projects that improve the supply of critical medicinal products to the Union market and ensure their continuous availability across the Member States, enhancing the overall security of supply within the Union.

This action should notably target project proposals that:

- a) relate to critical medicinal products for which, under the new pharmaceutical legislation, the vulnerability evaluation has identified a supply chain vulnerability or a high level of dependency, or, where that evaluation has not yet been concluded, for which the applicant demonstrates the existence of a vulnerability in the supply chain of the critical medicinal product concerned or of its active substance or key input within scope, and, in both cases, demonstrates how the project will address that supply chain vulnerability;
- b) where some manufacturing capacity already exists in the Union, contribute to the diversification of supply chains in several Member States, thus reducing the risk of geographical concentration of manufacturing in a single Member State, and help mitigate potential disruptions caused by regional crises, such as natural disasters or geopolitical tensions, ensuring a more resilient and secure supply of critical medicinal products across the Union;
- c) focus on expanding, creating or modernising manufacturing capacities rather than relocating existing production facilities within the Union, ensuring that the action leads to a net increase in the overall production of the critical medicinal products in the Union; and;
- d) demonstrate the capability of supplying markets in the Union efficiently with long-term viability and impact.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal¹⁵⁹, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

EXPECTED RESULTS AND IMPACT

This action is expected to contribute to reducing shortages of medicines, reinforcing supply chains, encouraging diversification and boosting manufacturing of critical medicines within the Union.

The Commission expects to fund one or more projects under this call addressing supply chain vulnerabilities, enhancing manufacturing capacity for critical medicinal products and their active substances, and supporting the adoption of key enabling technologies to improve security of supply across the Union.

¹⁵⁹ [Strategic Technologies for Europe Platform](#).

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal¹⁶⁰, 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 – HS-g-26-18	Q4/2026	EUR 40 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Enterprises from EU Member States (incl. social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit). Beneficiaries are expected to be stakeholders in the pharmaceutical industry and supply chain. Eligible applicants may include either a single enterprise or a consortium of relevant actors.

4.4. BIOTECH

HS-g-26-19 Call for proposals to support clinical trials for biotech medicinal products (DG SANTE)

POLICY CONTEXT

This action focuses on enhancing the Union's competitiveness of the biotech industry, supporting clinical trials in this field with the goal to improve availability of medicines in the Union. Over the past decade, the Union experienced a decline in clinical trials, with its global share dropping from 18% in 2013 to just 9% in 2023, while regions like China and the United States of America expanded their clinical trial activity due to more streamlined regulatory environments. In addition, the Union should maintain its leadership in biotechnology and leverage biological solutions to address diseases.

This action aims to further support the innovative approaches in the clinical trials processes and to enhance multinational clinical trials. By effectively implementing Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on

¹⁶⁰ [Strategic Technologies for Europe Platform](#).

medicinal products for human use¹⁶¹ ('Clinical Trials Regulation'), the Union can capitalise on a unified process, making it a premier location for clinical trials.

This aligns with broader Union priorities in the context of the clinical trials, including the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare¹⁶², the Draghi Report on the future of European competitiveness¹⁶³, the Letta report on the future of the Single Market¹⁶⁴ and the Strategy for European Life Sciences¹⁶⁵. The Commission proposal for a European Biotech Act adopted on 16 December 2025¹⁶⁶ further highlights the importance of harmonisation, streamlined process and reduction of the administrative burden in advancing biotechnology as a key driver of innovation and economic growth.

This action supports preparing the implementation of the amendments of the Clinical Trials Regulation under the Commission proposal for a European Biotech Act by encouraging the use of artificial intelligence and innovative technologies and approaches for designing clinical trials, such as the integration of decentralised elements.

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).

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

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to support the conduct of clinical trials in the Union for biotech medicinal products (e.g. biological medicinal products, advanced therapy medicinal products or vaccines). This action will support the Clinical Trials Regulation's goals of facilitating high-quality, efficient clinical trials in the Union, promoting health innovation, and ultimately delivering timely access to new therapies for patients.

Overall, the beneficiaries are expected to conduct the following activities:

- a) a multinational clinical trial in phase 1, 2 or 3 with innovative approaches covering at least three Member States. More specifically, the clinical trial shall include participants from several EU Member States and EEA countries associated to the EU4Health programme, ensure a gender-balanced approach in the participant recruitment, and carefully consider the inclusion of individuals from vulnerable populations;
- b) prepare the regulatory activities to submit a clinical trial application;

¹⁶¹ OJ L 158, 27.5.2014, p. 1, ELI: <https://eur-lex.europa.eu/eli/reg/2014/536/oj>.

¹⁶² [Mission letter](#) to Commissioner for Health and Animal Welfare.

¹⁶³ [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](#).

¹⁶⁴ [Much more than a market – Speed, Security, Solidarity. Empowering the Single Market to deliver a sustainable future and prosperity for all EU Citizens](#).

¹⁶⁵ [Strategy for European Life Sciences - Research and innovation](#).

¹⁶⁶ Proposal for a Regulation of the European Parliament and the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act) [COM/2025/1022 final](#).

- c) where applicable, prepare regulatory activities for the clinical development part of a future marketing authorisation;
- d) activity encompassing the engagement with relevant regulatory authorities prior to submission;
- e) if possible, incorporate decentralised elements, allowing certain trials or trial activities to be conducted remotely or across multiple sites;
- f) if possible, include application of AI tools (e.g. to enable faster patient recruitment, optimise protocol design);
- g) enhance data analysis and ultimately improving trial efficiency, including ensuring a sufficiently large sample size that enables meaningful conclusions.

Mandatory deliverables include:

- a) conduct of a multinational clinical trial;
- b) preparing regulatory material for clinical trial application;
- c) where applicable, preparing the regulatory material for marketing authorisation;
- d) preparing a report that documents the conduct and findings of the clinical trial activity.

Academia, non-for-profit organisations, start-up or SMEs will be encouraged to apply as they are at the forefront of innovation. A project that ensures the deployment of biotech medicinal products to patients located in several Member States will be encouraged.

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.

EXPECTED RESULTS AND IMPACT

Overall, the action seeks to fund one or more multinational clinical trials with innovative approaches contributing to improve accessibility of biotech medicinal products to patients in the Union, ensuring both improved health outcomes and economic growth within the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – HS-g-26-19	Q4/2026	EUR 10 900 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Following entities from EU Member States and EEA countries associated to the EU4Health programme (Norway and Iceland): academia and education establishments, research institutes and research organisations, hospitals and

		healthcare providers, enterprises (incl. social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit)
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4.5. SUBSTANCES OF HUMAN ORIGIN

HS-g-26-20 Call for proposals to strengthen resilience of the Union biotech manufacturing capacities – substances of human origin (DG SANTE)

POLICY CONTEXT

Substances of human origin ('SoHO') entities and establishments (like blood services or academic hospitals) organise for the supply of valuable and innovative therapies and services as essential part of the healthcare systems. These allow for transfusions for surgery or trauma care, stem cell therapies for cancer, tissue transplants for burns or heart diseases.

Supply continuity for several SoHO therapies is critical, and Chapter VIII of 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 application¹⁶⁷ ('SoHO Regulation') lists a series of measures to identify critical SoHO entities and to ensure this supply, at local, national and Union level. Several of these therapies are also essential in case of emergencies (e.g. emergency care or burn wound care) and some are of increasing interest in context of war/crisis situations (e.g. dried plasma as first line transfusion in front-line military situations).

While the supply of many SoHO is organised by public or non-profit services, they are subject to continuous innovation exchanged between academic centres across the Union. With this innovation comes increased specialisation of know-how and every new SoHO cannot be prepared in every Member State. While, for logistical and resilience reasons, it is not desirable that Union supply depends on one central facility, it is also not possible or efficient to have every type of SoHO prepared in each individual Member State.

Therefore, it is important to ensure and facilitate transfer of knowledge, know-how and SoHO within networks of SoHO establishments, each network focusing on providing and applying a few specialised SoHO therapies. This will allow each SoHO therapy to be prepared and provided locally in a similar way across the Union and consequently facilitate cross-border exchange and access for patients in the Union.

Hence, in case of local disruption within a SoHO establishment, supply can be supported/taken over by other SoHO establishments across the Union. This will strengthen the supply value chains for these important therapies.

¹⁶⁷ 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 196, 17.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>.

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.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to support different networks of SoHO entities to build streamlined capacity for the collection and production/preparation of specific SoHO therapies across the Union. This will facilitate the uptake and roll-out of innovative SoHO therapies, as well as the optimal use of (limited) SoHO resources/therapies available in the Union. The set-up of these supply chains can entail different steps, more or less in place depending on the type of SoHO.

Activities under this action can therefore entail:

- a) harmonisation, documentation, exchange and implementation of (new) SoHO practices on how to prepare and supply specific types of SoHO;
- b) training and knowledge exchange between SoHO entities and establishments on specific (new) SoHO practices;
- c) development of innovative/novel application for SoHO preparations, in cooperation between SoHO establishments and SoHO entities, including cooperation in the execution of pre-clinical studies and clinical outcome monitoring required to gather quality, safety and efficacy data, where needed covering evidence on equivalence and/or cost-efficiency;
- d) administrative authorisation of SoHO preparations, in cooperation with (multiple) SoHO competent authorities;
- e) investment in similar or equivalent equipment, devices and diagnostics;
- f) central/common supply monitoring, and SoHO exchange platforms, and/or clinical outcome monitoring.

The call can be organised over several lots, focusing on major types of SoHO (e.g. blood, plasma, skin or replacement tissues), and/or involving actors on different activities (i.e. donation, collection, processing, distribution/allocation, SoHO (pre-)authorisations/studies, use).

A total of up to five networks can be supported, delivering around 15 SoHO preparations. Expected beneficiaries are groups of SoHO establishments with expertise to prepare similar types of SoHO and/or Union societies representing such SoHO establishments. For the above-mentioned activities c) and d), each network is expected to consult one or more relevant SoHO competent authorities (without affecting the need for objective oversight), in order to provide early guidance to stakeholders on clinical outcome monitoring and administration.

The action will have to be organised in compliance with the principle of voluntary unpaid donation.

This action builds on the Draghi Report on the future of European competitiveness¹⁶⁸ which underlines the need for a fifth freedom in exchanging knowledge across the Union.

EXPECTED RESULTS AND IMPACT

¹⁶⁸ [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](#).

This action is expected to result in established capacity, to ensure supply continuity of critical SoHO across the Union, including more innovative therapies. This capacity will be in form of networks connecting SoHO establishments across the Member States.

This action will support implementation of provisions on supply continuity under Chapter VII of the SoHO Regulation and create Networks of Health Biotech clusters in the field of SoHO that will facilitate the testing, roll-out and uptake of innovative SoHO therapies.

This initiative streamlines healthcare practices for the supply of SoHO and enhances readiness of the healthcare services within the Union, in supplying and applying innovative biotech therapies. With this readiness, these healthcare services can also offer an established ecosystem for Union biotech companies that wish to develop, test and roll-out new healthcare innovations, like devices and platform technologies.

This action builds on the Draghi Report on the future of European competitiveness¹⁶⁹ which underlines the need for a fifth freedom in exchanging knowledge across the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – HS-g-26-20	Q4/2026	EUR 6 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Blood and tissue establishments, SoHO entities, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, expert networks, including ERNs – learned societies in the field of SoHO from EU Member States and EEA associated countries to the EU4Health programme (Norway and Iceland).

¹⁶⁹ [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](#).

4.6. MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES

HS-g-26-21 Direct grants to EU Reference Laboratories for the Union contribution on *in vitro* diagnostic medical devices supporting coordination of their activities to secure harmonisation of practices and meet legal obligations (DG SANTE)

POLICY CONTEXT

The implementation of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices¹⁷⁰ 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 Welfare¹⁷¹, the Council Conclusions on the Future of the European Health Union of June 2024¹⁷² and several debates in the Employment, Social Policy, Health and Consumer Affairs Council configuration (the ‘EPSCO Council’).

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 six 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 EURLs are to be considered transnational networks and therefore they are eligible for grants without a call for proposals in accordance with Article 198(1) point (d) of the Financial Regulation.

In the case of direct grants awarded without a call for proposals to transnational networks established 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.

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 EURLs network established in accordance with Article 100(5) of Regulation (EU) 2017/746 to fulfil their legal obligations.

This action will support tasks of the EURLs such as application of coordinated methods and process to secure harmonised practices, providing 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.

Synergies with other EU-funded initiatives will be sought, where appropriate.

¹⁷⁰ OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

¹⁷¹ [Mission letter](#) to Commissioner for Health and Animal Welfare.

¹⁷² [Council Conclusions](#) on the Future of the European Health Union of June 2024.

EXPECTED RESULTS AND IMPACT

This action will enable the EURLs 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 harmonisation for the 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-26-21	Q4/2026	EUR 3 500 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to the EU reference laboratories in accordance with Article 198(1), point (d), of Regulation (EU, Euratom) 2024/2509	HaDEA	Designated EU reference laboratories

HS-g-26-22 Direct grants to Member States' authorities to support reinforced market surveillance of medical devices and *in vitro* diagnostic medical devices to support effective and harmonised application across Member States (JAMS 3.0) (DG SANTE)

POLICY CONTEXT

Reinforced market surveillance is a key feature of the regulatory framework for medical devices and *in vitro* diagnostic medical devices. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices¹⁷³ and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices¹⁷⁴ require Member States' competent authorities to coordinate their market surveillance activities, cooperate and share information with each other and with the Commission to provide for a harmonised and high level of market surveillance across the Union. This harmonisation will ultimately streamline legal processes, reduce administrative burdens and simplify procedures, for the benefit of both national competent authorities and economic operators. Furthermore, it will promote greater consistency and predictability in how the regulatory framework is implemented across the Member States. This action supports the Commission's

¹⁷³ OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

¹⁷⁴ OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

simplification and burden reduction efforts in the context of the revision proposal¹⁷⁵ for Regulation (EU) 2017/745 and Regulation (EU) 2017/746, adopted in December 2025.

In addition, the provisions of the regulatory framework oblige the Commission to provide the necessary support to Member States' authorities to coordinate and ensure that the new regulatory system is efficiently and uniformly implemented at Union level. Considering the decentralised market access path for medical devices and *in vitro* diagnostic medical devices, and the reinforced obligations of the national competent authorities on market surveillance, there is a clear need to support Member States' authorities in aligning and strengthening coordination. Member States welcomed increased cooperation on market surveillance activities under Regulation (EU) 2017/745 and Regulation (EU) 2017/746, as well as the support provided in previous years through the EU4Health Programme. Furthermore, the industry has also called for harmonisation in the implementation of the legal framework between Member States. This joint action responds to these calls and will build on the previous joint action on market surveillance financed under the EU4Health Programme¹⁷⁶.

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.

The Union *acquis* on medical devices has been transposed in EEA and all EEA countries, including Liechtenstein, are part of the European medical devices regulatory network. Thus, and since Regulation (EU) 2017/745 and Regulation (EU) 2017/746 are implemented in EEA, including Liechtenstein, this joint action has the aim to ensure the same high level of patient safety across the Union and EEA by harmonising implementation of the Union medical devices *acquis*. Therefore, legal entities from Liechtenstein are eligible to participate in this joint action as associated partners without funding in accordance with Article 13(1), point (a)(iii), (2) and (3) of Regulation (EU) 2021/522.

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

- a) support the Commission in fulfilling its legal obligation to ensure cooperation and coordination among the Member States for the uniform and effective implementation of market surveillance. This joint action will enable collaboration and information

¹⁷⁵ https://health.ec.europa.eu/publications/proposal-regulation-simplify-rules-medical-and-vitro-diagnostic-devices_en Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, [COM/2025/1023 final](#).

¹⁷⁶ The Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices ([JAMS 2.0](#)).

exchange, establish procedures for signal detection and analysis of safety data, support assessment and case handling of devices presenting unacceptable risks, and strengthen cooperation with other relevant surveillance authorities and related activities such as post-market surveillance or vigilance;

- b) support the Commission in carrying out its legal requirements to assess measures with Union-wide relevance, including those concerning devices presenting an unacceptable risk and preventive health protection measures and allow for a harmonised application;
- c) ensure harmonised and efficient inspections of manufacturers, including e-commerce actors, across the Member States by supporting the cooperation and specialisation of the Member State inspectors and avoid discrepancies, in particular by:
 - facilitating the sharing of expertise and best practices especially on identified non-compliances, and the exchange of information and knowledge between inspectors;
 - further enhancing and implementing a common framework for joint inspections to facilitate the harmonisation of approaches at national level throughout the Union;
 - identification of available inspectors' expertise, developing a unified network of expertise and performing capacity building activities and training or re-training across the network;
- d) support joint inspections of economic operators or other relevant actors, to be performed by a team of inspectors and, with the required expertise, with a view to harmonisation of inspections at Union level and reduce discrepancies by:
 - contributing to a harmonised approach to inspections at Union level;
 - combining efforts when inspecting economic operator activities that are relevant at Union level, including non-Union based manufacturers;
 - establishing procedures for collaborating with other relevant authorities e.g. customs.

The action builds on the outcome of the JAMS 2.0 joint action that aimed to reinforce market surveillance between Member States by sharing best practices, training, knowledge, and resource to increase public health protection in the medical devices sector.

EXPECTED RESULTS AND IMPACT

The expected results include securing a smooth and timely implementation of the regulatory framework, in particular through more effective market surveillance activities, increasing coordination and work-sharing including cooperation with vigilance activities, in particular by harnessing the use of vigilance data.

Moreover, this joint action will result in capacity sharing and building up of expertise on market surveillance.

This joint action will contribute to the increased safety of medical devices by ensuring that non-compliant devices are kept off the Union market. Finally, this action is expected to result in streamlined and simplifying procedures for the benefit of both national competent authorities and economic operators.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
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Direct grants – HS-g-26-22	Q4/2026	EUR 3 330 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to Member States (joint action) in accordance with Article 198(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)

5. DIGITAL (DI)

DI-g-26-23 Call for proposals for European Health Data Space Readiness Package for secondary use of health data (DG SANTE)

POLICY CONTEXT

One of the key pillars of Regulation (EU) 2025/327¹⁷⁷ of the European Parliament and of the Council ('EHDS Regulation') is to facilitate the secondary use of health data across Member States. This will be achieved through the establishment of Health Data Access Bodies ('HDABs'), connected to the HealthData@EU cross-border digital infrastructure to facilitate the secure, efficient, and cross-border access to health data for the purposes of research, innovation, health policy-making and regulatory activities. HDABs deploy minimum key digital business capabilities such as Data Access Application Management Systems ('DAAMS'), national dataset catalogues (nHDsC), Secure Processing Environments ('SPEs'), connectors to the infrastructure, cross-border gateways, opt-out mechanisms, and transparency tools.

The Commission has so far supported Member States in setting up HDABs, deploying the minimum digital business capabilities and capacity building. In parallel, the Commission is developing the HealthData@EU central platform, including a suite of open-source components supporting these business capabilities. These modules — such as dataset catalogues, data quality and utility labels, or DAAMS — are now available for reuse by Member States and HDABs. The priority now is to enable their testing, adaptation, and coordinated deployment in a coherent and cost-effective manner.

Moreover, Member States had highlighted the need for a structured forum to exchange best practices on HDAB set-up and deployment, address issues early, co-create common procedures, and converge on practical solutions. To meet this need, in 2024, Member States initiated an EHDS Community of Practice ('CoP') bringing together HDABs and relevant competent authorities.

The TEHDAS2 Joint Action highlighted, in the draft guideline on a framework for collaboration¹⁷⁸, the relevance of the existing network of research infrastructures, collaborative initiatives, and domain-specific communities as a resource that the EHDS implementation process can draw upon and presented actionable recommendations towards a collaboration framework.

A reinforced action is therefore needed to avoid a risk of fragmentation and knowledge loss at the point when most Member States infrastructures will be coming live. The action should be directed at: supporting the testing of open-source components of the HealthData@EU platform; exchanging best practices and expertise to build capacity among Member States for technical implementation; organising training programmes, and promoting digital health literacy (Article 82, Article 83 and Article 84 of the EHDS Regulation).

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

OBJECTIVES, SCOPE AND ACTIVITIES

¹⁷⁷ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

¹⁷⁸ [Draft guideline on a framework for collaboration](#).

This action aims to foster Member State collaboration and accelerate their implementation of the EHDS for secondary use, as foreseen in the EHDS Regulation.

It will build on, by connecting and mutually reinforcing various services, documents and materials already developed, such as the EHDS Implementing Acts, TEHDAS2 joint action's¹⁷⁹ technical specifications and guidelines, the HealthData@EU infrastructure, training material developed by the EU4Health project on capacity building in the area of secondary use of health data, the Stakeholders Support activities, the Horizon Europe action on developing a Data Quality and Utility Label for the EHDS, and the Blueprint of digital business capabilities and workflows endorsed in the framework of the Community of Practice for health data access bodies.

The objectives are to:

- a) promote efficiency, interoperability and coherence across the Union by reducing fragmentation, and ensuring that Member States can benefit from common solutions to meet the requirements of the EHDS Regulation, through EHDS2 (secondary use) Implementation Labs - where Member States and stakeholders engage and jointly test and adapt open-source components from the HealthData@EU central platform, or other emerging open source components (e.g. AI tools developed by Member States or by the Commission, solutions developed by European research and digital infrastructures, collaborative initiatives, and domain-specific communities, etc.);
- b) strengthen collaboration and extend the EHDS Community of Practice for health data access bodies to exchange best practices and knowledge, anticipate, address and mitigate implementation challenges, facilitate harmonisation of processes, develop specific operational guidance (e.g. secure processing environments, data quality/metadata), foster collaborations between national HDABs, other relevant actors, e.g. European Research Infrastructure Consortia ('ERICs') and European Digital Infrastructure Consortia ('EDICs') and stakeholders (data holders, data users) and share solutions;
- c) reinforce capacity of HDABs, other relevant actors and stakeholders, through customised support services, collaborative implementation pilots, training and monitoring progress.

The scope of this action is an EU-wide targeted support to HDABs, involving and taking into account needs of data holders and data users engaged in EHDS secondary use of health data, with a view to bridge existing gaps and prepare for a smooth, coherent and harmonised operationalisation of services.

The activities within this action include:

- a) the establishment of the EHDS2 Implementation Labs, where Member States taking part in the EHDS operational activities and other relevant actors will jointly test, validate, adapt and deploy open-source components of the HealthData@EU central platform and other emerging solutions and AI tools
- b) the facilitation of the EHDS Community of Practice for health data access bodies, including development of operational guidance, and the validation, sharing or shared acquisition of technological solutions supporting HDABs digital business capabilities where no ready-to-use open-source solution is made available at EU level (e.g. AI tools for metadata discovery, data access application screening, data preparation for secure

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<https://tehdas.eu/>.

processing, data linkage, Secure Processing Environment (‘SPE’) starter kit packages and related support services, ensuring compliance with EHDS and General Data Protection Regulation (‘GDPR’) requirements; opt-out management systems, interoperable with national eID infrastructures to allow the exercise and management of rights);

- c) building broader capacity and strong operational collaboration among Member State competent authorities, HDABs and other relevant actors, e.g. ERICs and EDICs, and stakeholders (data holders and data users);
- d) structured collaboration with stakeholders, collaborative benchmarking, knowledge sharing and problem resolution in setting up and operationalising HDABs;
- e) the monitoring of the progress and Member States’ readiness in the area of secondary use of health data and HDAB maturity in view of preparation of the Commission progress report in relation to the implementation of the EHDS Regulation (Art. 102 (4)).

Mandatory deliverables:

- a) a report on the frequency, activities and operation of the EHDS2 Implementation Labs
- b) a toolbox with open-source technological solutions that support the implementation of the secondary use under the EHDS Regulation, including open-source modules, blueprints and workflows covering the main EHDS business capabilities for secondary use (e.g. data access application management, dataset descriptions, HealthData@EU connectors, Secure Processing Environment (SPE), opt-out mechanism and transparency, fees and IP rights);
- c) a consolidated peer-learning and benchmarking package (report with peer-learning events, material exchange, knowledge platform, and a problem resolution log);
- d) a package with training materials for specific stakeholder groups (e.g. healthcare providers, industry, research organisations, domain specific health professionals, public authorities) to be channelled through adequate EU platforms including relevant EHDS stakeholder platforms;
- e) a maturity monitoring framework (leveraging the existing HDAB maturity model) and annual reports.

EXPECTED RESULTS AND IMPACT

This action is expected to increase the capacity of Member States and key stakeholders to ensure a well-functioning EHDS, to advance research, promote innovation and the competitiveness of European healthcare industry, and improve evidence-based policy making.

In addition, this action is expected to ensure readiness of Member States’ competent authorities, HDABs, other relevant actors and stakeholders in rolling-out and taking-up the EHDS infrastructure and services, as stipulated by the EHDS Regulation. It will also enhance the resilience and efficiency of national health systems, while demonstrating the added value of European cooperation in digital health.

This action also intends to ensure that investments at EU and national level translate into coherent, future-proof infrastructures for secondary use of health data.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
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Call for Proposals – DI-g-26-23	Q4/2026	EUR 14 350 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States’ authorities (public health authorities), academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, ERICs and EDICs; enterprises (incl. social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit).

DI-g-26-24 Call for proposals for Artificial Intelligence for smart European Health Data Space compliance support (DG SANTE)

POLICY CONTEXT

Regulation (EU) 2025/327 of the European Parliament and of the Council¹⁸⁰ (‘EHDS Regulation’) aims to facilitate the secure, efficient, and cross-border access to electronic health data across Member States for primary categories of health data (such as ePrescriptions and Patient Summaries) and of secondary use of health data for research, innovation, health policy-making and regulatory activities.

Embedding the application of artificial intelligence (‘AI’) solutions in both clinical workflows and in the administrative processes of data holders and Health Data Access Bodies (‘HDABs’), facilitates and accelerates stakeholders’ compliance with the EHDS Regulation. On the one hand, AI can reduce administrative burden on health professionals and staff, freeing-up time for the provision of healthcare services and improving patient experience. On the other hand, AI solutions have the potential to improve data quality, interoperability and findability, accelerate and reinforce business processes and document flow, which also facilitate the work of data holder and HDABs.

As the EHDS Regulation will enter into application, a reinforced Commission action is needed to help EHDS stakeholders – health professionals, hospitals, HDABs, data users and other relevant actors – comply with their obligations under the EHDS Regulation in an efficient way, avoiding fragmentation, at the time when most Member States infrastructures will be coming live.

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

¹⁸⁰ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to boost the design, development and future deployment of AI solutions that support and speed up stakeholders' compliance with the EHDS Regulation for both primary and secondary use, reducing administrative burdens and freeing up health professionals' time to focus on their core business: providing healthcare services.

The objectives are to:

- a) promote and advance data holders, National Contact Points for Digital Health ('NCPDHs') and HDABs readiness and efficiency to comply with the EHDS Regulation through the integration and validation of dedicated AI solutions, including open-source tools, in administrative workflows encompassing data collection, description, preparation, and application management, with the aim to enhance data usability and integrity, data quality, and interoperability at source – both for primary and secondary use – across Member States' health systems;
- b) promote the deployment of Ambient Clinical Intelligence in healthcare environments (e.g. AI scribes), that generate structured, high-quality data that feed directly into Electronic Health Records ('EHRs'), so that data, documentation and decision-support flow seamlessly, reducing administrative burdens for healthcare professionals, medical staff and patients.

The scope of this action is to support the design, testing, and validation of AI tools or other tools to support healthcare providers, NCPDHs, HDABs and data holders to comply with the requirements set in the EHDS Regulation for both primary and secondary use.

For primary use, the action aims to alleviate administrative burden, bridge existing gaps and improve interoperability at source to allow a smooth operationalisation of services in clinical workflows. Simultaneously, this will aim to improve data quality and usability as needed for AI-based solutions to be used by data holders and HDABs in secondary use. The action will prioritise support to the design of common, reusable, and customisable AI components that can be easily adopted by different actors in the healthcare sector. It will build on relevant European initiatives (e.g. 1+Million Genome Initiative¹⁸¹, European Genomic Data Infrastructure¹⁸², European Cancer Imaging Initiative¹⁸³, European Federation for CANcer IMages project - EUCAIM¹⁸⁴ and other ongoing projects funded under Horizon Europe, EU4Health and Digital Europe programmes, among others) to ensure complementarity and scalability, contributing to the competitiveness and coherence of the European digital health ecosystem.

Activities:

The action aims to support the design, piloting and testing and validation of AI tools and components that facilitate compliance with the EHDS Regulation for both the primary and secondary use of health data, through common and reusable solutions. Specifically, activities under this action aim to:

- a) support EHR system manufacturers in designing, piloting and validating AI tools, including open-source models, that improve data quality at source, enhance data usability and integrity, both for primary and secondary use. Concrete examples include,

¹⁸¹ [European '1+ Million Genomes' initiative | Shaping Europe's digital future.](#)

¹⁸² [European Genomic Data Infrastructure \(GDI\) project.](#)

¹⁸³ [European Cancer Imaging Initiative | Shaping Europe's digital future.](#)

¹⁸⁴ [Home - Cancer Image Europe.](#)

among others: improving data quality at source; automating the generation of structured information such as patient summaries; assisting data holders in dataset preparation to respond to data users requests to access data via the HDABs;

- b) promote the design, development and validation of AI tools, including open-source modules, to support HDABs and health data holders in managing their compliance with the EHDS Regulation, including automating dataset description and validation, data preparation, data access application management, and estimation of costs and fees;
- c) support the development, iterative piloting and validation of Ambient Clinical Intelligence applications in controlled environments (e.g. AI scribes in clinical settings), ensuring that outputs align with EHDS data quality and interoperability requirements and based on collaboration and feedback from direct users and relevant stakeholders;
- d) foster collaboration, knowledge sharing and alignment between EHR vendors and AI developers, standardisation bodies, data holders, HDABs, and healthcare providers to ensure alignment with EHDS interoperability, metadata, and data quality frameworks.

EXPECTED RESULTS AND IMPACT

The action is expected to improve the readiness of relevant stakeholders to comply with the EHDS regulation. Specifically, it will result in:

- Collaborative testing environments enabling cooperation between EHR vendors, AI developers, HDABs, healthcare providers and standardisation bodies.
- Validated AI solutions and reusable components supporting EHDS compliance, including tools for improving data quality at source, automating dataset description and metadata generation, assisting data preparation, and supporting application management processes by HDABs.
- Piloted and tested AI tools integrated into clinical and administrative workflows (e.g. ambient clinical intelligence, AI-assisted documentation), demonstrating their capacity to reduce administrative burden and generate structured, high-quality data compatible with EHDS interoperability requirements.

By leveraging AI tools, this action is expected to support and accelerate stakeholders' compliance with the EHDS Regulation in an efficient way, reducing compliance costs, administrative burden for health professionals, national competent authorities, HDABs, data holders and data users, and advancing cross-border health services, as well as research, innovation and the competitiveness of European healthcare industry.

Moreover, this action intends to position EHDS as a key catalyst that triggers modernisation and digitisation of European health systems.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – DI-g-26-24	Q4/2026	EUR 3 000 000
Procedure type	Implemented by	Type of applicants targeted

Open call for proposals (action grants)	HaDEA	Member States' authorities (public health authorities) international organisations, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers ERICs and EDICs, civil society organisations: associations, foundations, NGOs; enterprises (incl. social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit).
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DI-g-26-25 Call for proposals for advancing Artificial Intelligence in healthcare through local performance assessment (DG SANTE)

POLICY CONTEXT

Healthcare systems face unprecedented challenges, including rising demand due to an ageing population, increasing prevalence of chronic and complex conditions, rising costs, and shortages in the healthcare workforce. Following a Commission Study on the deployment of AI in healthcare¹⁸⁵, it is evident that European healthcare systems are and will be faced with significant challenges, raising concern over their long-term sustainability. For example, 40% of EU citizens aged 65 and above live with at least two chronic conditions. The proportion of the EU population aged 65 and above has increased from 16% in 2000 to over 21% in 2023, with projections indicating a further rise to nearly 30% by 2050.

Artificial intelligence (AI) is often seen as a transformative tool that can contribute to address these challenges. However, AI adoption in clinical practice remains limited. Regulatory and policy developments, including the framework for medical devices ('MDR')¹⁸⁶ and *in vitro* diagnostic medical devices ('IVDR')¹⁸⁷, the Artificial Intelligence Act ('AIA')¹⁸⁸, Regulation (EU) 2025/327 on European Health Data Space ('EHDS Regulation')¹⁸⁹ and the revised Product Liability Directive ('PLD')¹⁹⁰ aid in this direction, but deployment challenges persist. AI must be scaled responsibly to boost up innovation in the EU, deliver real benefits and build public and clinical trust.

¹⁸⁵ European Commission: Directorate-General for Health and Food Safety, EEIG, Open Evidence and PwC, *Study on the deployment of AI in healthcare – Final report*, Publications Office of the European Union, 2025, <https://data.europa.eu/doi/10.2875/2169577>.

¹⁸⁶ OJ L 117, 5.5.2017, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

¹⁸⁷ OJ L 117, 5.5.2017, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

¹⁸⁸ OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>.

¹⁸⁹ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

¹⁹⁰ OJ L, 2024/2853, 18.11.2024, ELI: <http://data.europa.eu/eli/dir/2024/2853/oj>.

In October 2025 the Commission launched the Apply AI Strategy¹⁹¹ with comprehensive measures to boost the uptake of AI across strategic sectors including healthcare, and actions supporting the validation and deployment of AI in healthcare.

One of the key challenges is the variable real-world performance of AI systems across different healthcare settings. AI tools may not generalise well due to differences in patient populations, workflows, data quality, clinical guidelines and human behaviour, among others. As identified in the Commission Study on the deployment of AI in healthcare, the lack of local performance assessment protocols is a major obstacle. EU level regulatory validation performed as part of the regulatory process ('AIA', 'MDR', 'IVDR' etc.) ensures baseline safety and performance that would be confirmed with localised evaluation in diverse clinical settings. Addressing this gap is essential to advance trust, innovation and effective deployment of AI in healthcare.

This action implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (f), (g) and (h), of Regulation (EU) 2021/522. Moreover, this action will build on the results, in particular the considerations on local performance assessment, from the COMPASS-AI project, co-funded under the EU4Health Programme and establish synergies with the projects funded under DIGITAL programme under DIGITAL-2026-AI-09-SOLUTIONS-CANCER-STEP and DIGITAL-2026-AI-PILOTING-10-SCREENING. in the context of the Apply AI flagship action on the European network of AI-powered advanced screening centres¹⁹².

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to:

- a) prototype a European framework for local AI performance assessment;
- b) demonstrate feasibility and value by piloting the approach in selected clinical settings, e.g. cancer;
- c) build trust and safety evidence by capturing local variations in patient populations, workflows and data quality;
- d) prepare for scale-up by producing standards, methodologies and demonstrators that can be integrated into future EU actions;
- e) accelerate innovation and competitiveness by providing developers with EU-wide feedback loops and trusted performance benchmarks.

The scope of this action is to design and test a prototype framework for local AI performance assessment, complementing EU-level regulatory validation. With a limited but high-impact scope, the action will:

- a) focus on 1–2 Clinical AI Testbeds ('CATs') in hospitals, testing AI systems in real-world settings (e.g. radiology and neurology);
- b) establish a core AI Expert Group to develop draft validation standards and playbooks;
- c) build a light Digital Performance Prototype ('DPP') that connects testbeds and developers, offering dashboards and initial benchmarking tools;
- d) produce evidence from pilot studies that can guide a larger-scale European roll-out.

The activities include:

¹⁹¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0723>.

¹⁹² <https://digital-strategy.ec.europa.eu/en/policies/ai-screening-centres>.

1) AI Expert Group:

- a) assemble a focused group of 10–15 experts (technical, clinical, legal);
- b) develop draft local validation standards, playbooks and KPIs for performance testing.

2) Develop Prototype Validation Methodologies:

- a) design evidence-based protocols for testing AI tools in real-world hospital workflows;
- b) document performance-impacting elements (data variation, workflow, explainability).

3) Pilot 1–2 Clinical AI Testbeds (CATs):

- a) partner with 1–2 hospitals in diverse Member States;
- b) test selected AI tools in real-world scenarios, capturing local determinants of performance;
- c) provide structured feedback to developers.

4) Digital Performance Prototype (DPP):

- a) build a minimal viable platform connecting testbeds and developers;
- b) provide basic dashboards and benchmarking functions;
- c) prepare technical specifications for a full-scale platform in the future.

5) Pilot Demonstration and Evaluation:

- a) run pilot studies on 2–3 AI tools; building on the knowledge from Activity 4);
- b) demonstrate the added value of local testing (e.g. improved accuracy, trust impacts, reduced clinical risk);
- c) publish a scalability and policy roadmap; in this context also show how data, tools and services from EHDS and other EU frameworks/infrastructures could be integrated to aid local performance testing and post-deployment monitoring.

EXPECTED RESULTS AND IMPACT

This action is expected to:

- a) deliver a prototype European framework for local performance assessment of AI in healthcare, validated through pilot use cases;
- b) demonstrate trustworthy deployment by showing how local variations (data, workflows, populations) can be systematically captured;
- c) provide draft tools and playbooks for healthcare providers to evaluate and select AI solutions adapted to their context;
- d) test a feedback loop for innovation, allowing AI developers to refine models based on hospital data and real-world interactions;
- e) produce first evidence of cross-border collaboration, through 1–2 testbeds sharing insights and methodologies;
- f) publish a roadmap for scale-up, outlining how the prototype can evolve into a full EU-wide framework (compliant with EHDS Regulation, AIA etc.);
- g) create visibility and momentum for Europe's leadership in trustworthy AI in healthcare.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
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Call for Proposals – DI-g-26-25	Q4/2026	EUR 1 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States’ authorities (public health authorities), international organisations, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, civil society organisations: associations, foundations, NGOs; enterprises (incl. social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit).

DI-g-26-26 Call for proposals for designing the ecosystem for multimodal Artificial Intelligence driven prevention and early detection of neurodegenerative diseases (DG SANTE)

POLICY CONTEXT

Neurodegenerative diseases are among Europe’s most pressing and costly health challenges. For example, as regards dementia, the number of people with the disease in Europe will almost double by 2050 increasing to 14 298 671 in the Union and 18 846 826 in the wider European region¹⁹³. The economic impact is equally overwhelming: in 2019, the total societal cost of dementia in Europe was estimated at EUR 392 billion. In the absence of major changes advances in the risk prediction, early detection, prevention and treatment, both societal and economic costs are projected to rise sharply¹⁹⁴.

While artificial intelligence (‘AI’) holds transformative potential for identifying subtle early markers of disease, current efforts are fragmented and largely focused on application development or retrospective analysis. Critically, there are gaps in the clinical, scientific, and ethical ecosystem required to make AI-based neurodegenerative risk prediction and early detection trustworthy, actionable and aligned with public health needs.

The Union is uniquely positioned to lead in this space through strategic initiatives such as the European Partnership for Brain Health (‘EP BrainHealth’) ¹⁹⁵, Europe's Digital Infrastructure for Brain Research (‘eBRAINS’)¹⁹⁶, Regulation (EU) 2025/327 of the European Parliament

¹⁹³ [Prevalence of dementia in Europe | Alzheimer Europe.](#)

¹⁹⁴ [future-proofing-the-ad-healthcare-journey.pdf.](#)

¹⁹⁵ [Strengthening brain health research - EP BrainHealth.](#)

¹⁹⁶ [EBRAINS RI - Europe's Digital Infrastructure for Brain Research.](#)

and of the Council ('EHDS Regulation')¹⁹⁷, the 1+ Million Genomes Initiative ('1+MG')¹⁹⁸ and in complementarity with existing projects such as AI-Mind¹⁹⁹. These efforts will provide unprecedented access to multimodal data, ranging from imaging and genomics to wearables and lifestyle metrics, but we need to build a unifying framework for translating AI neurogenerative risk predictions into meaningful actions. This project addresses that gap.

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

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to design a prototype scientific, clinical and ethical ecosystem that enables multimodal AI-driven early prediction and detection of neurodegenerative diseases. These foundations will support current and future AI solutions in this domain. The results will be valuable for the multidisciplinary community developing and scaling AI tools, and in particular in the field of neurodegenerative diseases, from AI developers to end users (healthcare professionals).

The activities conducted under this action will focus on:

1) Mapping scientifically valid data inputs + developing a multimodal AI prototype platform:

- a) identify and validate the most relevant data types (e.g. Metadata Radiological Image ('MRI'), biomarkers, speech, genomics, cognitive scores, lifestyle, socio-demographic factors) for early AI-driven prediction of neurodegenerative disease risk;
- b) provide evidence-based guidance on which combinations of data are most predictive and feasible to collect across EU Member States;
- c) develop a modular, research-oriented AI prototype platform capable of ingesting and analysing multimodal data;
- d) as part of this platform, the consortium will engage in the training, validation and testing as well as piloting in real clinical settings an exploratory predictive AI model, using anonymised data from research cohorts. This model will simulate early risk prediction and enable meaningful testing of clinical response protocols and guidelines;
- e) the platform and model are non-commercial reference tools, designed to support ecosystem development and future responsible innovation.

2) Foster collaboration between experts:

- a) assemble a high-level, interdisciplinary network of AI developers, clinicians, neuroscientists, ethicists, patient advocates, and data specialists;
- b) create the foundation for a European Brain Health AI Community that can shape future EU actions and standard-setting. This Community may later merge with other established community(ies) at EU level.

3) Design the clinical follow-up plan post-prediction, including ethical aspects:

¹⁹⁷ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.
¹⁹⁸ [European '1+ Million Genomes' initiative | Shaping Europe's digital future.](#)
¹⁹⁹ [EU Funding & Tenders Portal.](#)

- a) provide evidence for defining pathways managing the aftermath of a person receiving an AI-based risk assessment;
- b) develop a structured care pathway combining lifestyle advice, pharmaceutical options, close monitoring (e.g. MRI frequency), and cognitive support.

4) Developing evidence-based guidelines:

- a) translate insights into clinical evidence-based guidelines (with possible involvement of relevant medical societies) for managing AI-predicted neurodegenerative risk;
- b) align with existing clinical protocols where possible and inform updates to public health guidance.

5) Small-scale pilot to test the pathway:

- a) pilot the end-to-end process using (synthetic) existing risk prediction models.
- b) focus on process testing:
 - is the data feasible to collect?
 - do clinicians feel equipped to act on AI outputs?
 - how do patients respond to early preventive advice?
- c) extract lessons learnt from the pilot that could help finetuning the project deliverables.

EXPECTED RESULTS AND IMPACT

This action is expected to deliver the following results:

- a) publish a scientific map including prioritised multimodal data inputs for early neurodegenerative disease prediction and the relevance for specific types of neurodegenerative diseases;
- b) develop a multimodal AI prototype platform;
- c) train, validate and test an exploratory predictive AI model;
- d) provide a clinician-informed response protocol for acting on AI-based risk outputs;
- e) draft clinical guidelines and practical recommendations for integration into health systems, including the ethics dimension;
- f) provide an interdisciplinary EU expert network ready to scale up into a possible permanent reference group;
- g) provide insights from a real-world pilot testing of the practical and ethical implications of acting on early risk signals.

The expected impacts are:

- a) to create the clinical, scientific, and ethical backbone needed to deploy AI responsibly in brain health, e.g. in AI neurodegenerative risk prediction;
- b) to support the EHDS, 1+MG, and EP Brain Health by clarifying use cases and priorities for preventive neurology;
- c) to avoid duplication of commercial efforts while enabling trustworthy public-private innovation;
- d) to lay the groundwork for a future public-private partnerships grounded in validated data needs, actionable guidelines and stakeholder trust.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for Proposals – DI-g-26-26	Q4/2026	EUR 1 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States' authorities (public health authorities), international organisations, academia and education establishments, research institutes and research organisations, hospitals and healthcare providers, ERICs and EDICs, civil society organisations: associations, foundations, NGOs; enterprises (incl. social enterprises and not for profit) in the field of public health, private entities (for profit/not for profit) with expertise in neurodegenerative diseases and other relevant areas.

6. OTHER ACTIVITIES (OA)

OA-g-26-27 Call for proposals to contribute to the organisation of conferences (DG SANTE)

POLICY CONTEXT

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

As a result of this action, conferences will be delivered by entities with proven expertise in organising public health events, ensuring a professional standard of execution and a well-defined, representative participant base (from Member States and countries associated to the EU4Health Programme), diverse organisations, and areas of expertise. This representativeness will strengthen the legitimacy and relevance of the discussions, ensuring that outcomes reflect the full range of perspectives needed to address the challenges at stake.

The presence of high-level speakers together with a substantial base of participants from all relevant fields will generate authoritative, cross-sectoral dialogue, producing concrete input and recommendations that feed directly into EU health policy development.

Targeted communication activities reaching the general public, specific population groups, and health professionals will increase awareness, understanding, and ownership of the European Health Union and its initiatives. This will significantly extend the impact of the conferences well beyond participants to the wider public.

By preserving a Union-wide dimension and a focus on cross-cutting policy issues rather than a specific condition or disease, the action will drive greater coherence and cooperation between Member States on shared health priorities. This will directly contribute to building a stronger, more integrated European Health Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for proposals – OA-g-26-27	Q4/2026	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

OA-g-26-91 Call for proposals for operating grants in 2027 to non-governmental organisations: financial contribution to the functioning of health non-governmental organisations implementing one or more specific objectives of Regulation (EU) 2021/522 (DG SANTE)

POLICY CONTEXT

Non-governmental organisations (‘NGOs’) are contributing to public health at Union, national and local levels. In particular where they provide services directly to patients and individuals. They are in some cases, such as emergencies, in the first line of action.

Health NGOs can also contribute to addressing current health challenges and supporting the implementation of health policy priorities at local, national and Union level, by that contributing to the EU health priorities as presented below.

Completing the European Health Union is a priority for the coming years in the area of European public health policy.

In the coming years, stepping up the Commission’s work on preventive health, ensuring a comprehensive approach to health promotion and disease prevention across the life course will be central to the execution of the programme. Effective prevention measures will reduce the burden of non-communicable diseases, helping to lighten the load on healthcare systems and supporting healthy longevity. The implementation of Europe’s Beating Cancer Plan will

continue, as well as the work on mental health, and the implementation of the Safe Hearts Plan addressing the key challenges across the Union related to cardiovascular health. Moreover, it will be important to address risk factors, such as the use of tobacco, and to continue the work on anti-microbial resistance as one of the major threats to health.

A particular focus is on critical medicines, to address the severe shortages of medicines and reduce dependencies relating to critical medicines and ingredients, as well as to ensure the supply of affordable medicines. The demographic changes, in particular the ageing society, challenge the sustainability of health systems. Patients and health systems need to have access to sustainable, efficient, equitable, and affordable high-quality medicinal products, including in the cross-border context, to fully benefit from those medicinal products on the basis of transparent, consistent, and patient-oriented medical information.

Another priority is the implementation of the European Health Data Space, with immediate next interventions focused on artificial intelligence and genome sequencing capacities.

The operating grants linked to a specified timeframe and specific measurable outputs are intended to provide support to health NGOs that pursue one or more of the general objectives (Article 3, points (a) to (d), of Regulation (EU) 2021/522) and through the specific objectives defined in Article 4, points (a) to (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective is to facilitate the participation of health NGOs in activities that are necessary to implement one or more specific objectives of the EU4Health Programme. Operating grants should provide support to their functioning in 2027 for activities including awareness raising on various health aspects, communication and dissemination, capacity building and training, expert collaboration and networking.

Activities proposed must comply with Commission Guidance on the funding for activities related to the development, implementation, monitoring and enforcement of Union legislation and policy²⁰⁰.

EXPECTED RESULTS AND IMPACT

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

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

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

²⁰⁰ [Guidance on the funding for activities related to the development, implementation, monitoring and enforcement of Union legislation and policy.](#)

Call topic/sub-topic	Indicative call publication	Indicative Budget
Call for proposals – OA-g-26-91	Q4/2026	EUR 1 800 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (operating grants for 2027)	HaDEA	Health NGOs

B. PROCUREMENT

The overall allocation reserved for procurement contracts in 2026 amounts to EUR 352 547 039.

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

In 2026, 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 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-26-28 EU FAB - Ever-warm facilities for vaccines production (DG HERA)

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

EU FAB will make available a network of ‘*ever-warm*’ production capacities for 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 able to respond to future health threats. This action will support the large-scale production of vaccines in the Union, to maintain and quickly guarantee access to sufficient production capacity in cases of public health emergency. Facilities supported under this action 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 agreed vaccines, upon request and within the requested timeframe.

Under this action, additional activities can also be supported, including for example modelling of manufacturing capacity of selected platforms to inform the Commission on possible surge volumes or existing points of failure.

The objective is to ensure that sufficient and agile manufacturing capacities for defined vaccine technology platforms (e.g. mRNA-based vaccines, protein-based vaccines and vector-based vaccines) are kept operational 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 for European vaccine manufacturing.

The expected result of this action is to guarantee quicker access to sufficient manufacturing capacities for vaccines at Union level in case of a future public health emergency and to respond to global obligations, as well as promote informed-based decision-making. 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 the required solid and reliable supply chains for vaccine production.

This action will also support the modernisation, expansion and next iteration of the EU FAB model, considering technological developments, surge capacities and lessons learnt, reinforcing the alignment with priorities described in the Medical Countermeasures and Stockpiling Strategies as well as the contribution to EU strategic autonomy.

This award procedure may affect security and/or public order of the Union and/or its Member States, as activities are aimed at ensuring availability of medical countermeasures, specifically during a health crisis. The availability of medical countermeasures has been identified, among others, as a critical element of economic security in the “*Joint Communication to the European Parliament and the Council on Strengthening Economic Security*”²⁰¹, as dependencies in this area may create systemic vulnerabilities requiring targeted measures to enhance resilience and reduce such dependencies. Therefore, specific conditions may be applied to award procedures under this action in accordance with Article 136 of the Financial Regulation.

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 actions under other Union funding programmes, such as 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), point (a)(iii), of the STEP Regulation and meets the condition under Article 2(2), point (b).

Indicative type of contracts/supply: new (multi-sourcing) framework contract(s), open call for tenders, use of existing framework contracts for the reservation of capacities and priority rights for manufacturing of MCMs²⁰², or other procurement procedures

Indicative budget for this thematic area: EUR 165 000 000

Implementation by: HaDEA

CP-p-26-29 EU FAB+ - Ever-warm facilities for MCMs production (DG HERA)

Following the announcement of a possible EU FAB expansion under the Medical Countermeasures Strategy²⁰³, this action aims at developing an EU FAB like approach towards other MCMs categories than vaccines, such as therapeutics, (including MCMs that are critical medicines), personal protective equipment, or diagnostics.

EU FAB+ is a targeted response to both the Commission’s policy priority of ensuring access and availability of key MCMs and stakeholder demands, ensuring the EU is better equipped to respond to future health emergencies with speed, autonomy, and resilience. This new initiative should bring an enhancement of:

- Security of supply of MCMs relevant for crisis response, ensuring sustained readiness across multiple potential crisis.
- Strategic autonomy by ensuring that the EU capacity of MCM’s is maintained and security of supply improved.

²⁰¹ [JOIN\(2025\) 977 final](#).

²⁰² Framework contracts established under the EU4Health 2022 Work Programme action “*CP-p-22-01.01 Ever-warm facilities (EU FAB) for vaccines and therapeutics production - European Health Emergency Preparedness and Response Authority (HERA)*”.

²⁰³ [Medical Countermeasures Strategy](#).

The action will address topics such as innovative manufacturing of APIs and related materials as well as tackling technological vulnerabilities to enhance supply security, including biomanufacturing alternatives.

It will build on action CP-p-25-35 (*‘Manufacturing investments and manufacturing capacity reservation contracts to strengthen supply of medical countermeasures’*) and it will seek the establishment of long-term contractual relationships with manufacturers by reserving capacity (e.g. manufacturing scalability, flexibility and virtual stockpiling) of the selected MCMs. Specifically, contracts will be set up with selected tenderers, for a defined duration, corresponding to the expected capacity reservation. The activation of such capacities can be foreseen in the upcoming event or in the materialisation of a crisis, in which contractors will be expected to produce and/or deliver the reserved MCMs.

Under this action, additional activities can also be supported, including for example modelling of manufacturing capacity of selected platforms and/or prototypes to inform the Commission on possible surge volumes or existing points of failure.

This award procedure may affect security and/or public order of the Union and/or its Member States, as activities are aimed at ensuring availability of medical countermeasures, as well as promote innovative manufacturing techniques, including through the use of novel biotechnologies. Innovate biomanufacturing has been identified as a strategic technology essential for reducing the Union’s strategic dependencies and strengthening its economic and industrial resilience in Regulation (EU) 2024/795 (*‘STEP Regulation’*), while the importance to guarantee the supply of APIs in the Union has been flagged as a critical component in the *“Pharmaceutical Strategy for Europe.”*²⁰⁴ Therefore, specific conditions may be applied to award procedures under this action in accordance with Article 136 of the Financial Regulation.

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 actions under other Union funding programmes, such as Horizon Europe. It implements the EU4Health Programme’s general objective of protecting people in the Union from serious cross-border threats to health as well as 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.

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

Indicative type of contracts/supply: new (multiple-sourcing) framework contract(s) for the reservation of capacities and priority rights for manufacturing of MCMs, open call for tenders or any other procurement procedures.

Indicative budget for this thematic area: EUR 15 000 000

Implementation by: HaDEA/HERA

²⁰⁴

[COM\(2020\) 761 final.](#)

CP-p-26-30 Support to speed up the development of, access to and/or uptake of medical countermeasures - MCM Accelerator (DG 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 aims to contribute for the implementation of "MCM Accelerator" and "Medifence" initiatives described in the Medical Countermeasures Strategy²⁰⁵, including support for development, access and uptake of MCMs addressing health threats prioritised by the Commission, e.g. against chemical, biological, radiological and nuclear ('CBRN') threats, also allowing, where relevant, for rapid deployment in outbreak, accident, attack, biosecurity, and/or conflict scenarios.

This action shall support the development of MCM, such as high-quality, effective and safe medicinal (e.g. vaccines, therapeutics) and non-medicinal (e.g. PPEs, diagnostics, self-administration devices, biosecurity equipment) MCMs, including the ones in advanced development phases, also taking in consideration opinions issued by the Clinical Trial Coordination Mechanism group (CT-CM). It will build on previous action "CP-p-25-36 - Support to speed up the development of, access to and/or uptake of medical countermeasures". 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, putting on the market and/or deployment of innovative and/or repurposed MCMs for treating, preventing, detecting or diagnosing priority health threats, e.g. for CBRN threats;
- 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;

Necessary measures (including, where clinically or epidemiologically indicated, biocontainment resources along the patient journey from suspected case through diagnosis, treatment, follow-up, and post-recovery) may be supported to ensure adequate patient care and safe MCM deployment.

This award procedure may affect security and/or public order of the Union and/or its Member States, as activities may be aimed at developing MCM that can have dual-use function. CBRN-related products and services may include critical technologies or defence strategic assets that are broadly identified as requiring special protective measures – e.g. under the Regulation (EU) 2019/452²⁰⁶ or under the Commission Recommendation (EU) 2023/2113²⁰⁷. Therefore, specific

²⁰⁵ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS - Preparing the EU for the next health crisis: a Medical Countermeasures Strategy. [COM\(2025\) 529 final](#).

²⁰⁶ [Regulation \(EU\) 2019/452 of the European Parliament and of the Council of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union](#).

²⁰⁷ [Commission Recommendation \(EU\) 2023/2113 of 3 October 2023 on critical technology areas for the EU's economic security for further risk assessment with Member States](#).

conditions may be applied to award procedures under this action in accordance with Article 136 of the Financial Regulation.

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 autonomous capabilities and preparedness for future health emergencies, in synergy with Horizon Europe and/or European Defence Fund. It implements the EU4Health Programme's general objectives of protecting people in the Union from serious cross-border threats to health and 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), point (a).

Indicative type of contracts/supply: new (multi-sourcing) framework contracts, use of existing framework contracts, open call for tenders or any other procurement procedure

Indicative budget for this thematic area: EUR 86 000 000

Implementation by: HaDEA/HERA

CP-p-26-31 Support to the Commission on gathering intelligence on priority threats and medical countermeasures (DG HERA)

The Commission has carried out a Health Threat Prioritisation 2026 Assessment for Medical Countermeasures which has identified four priority threat categories: respiratory or contact-based viruses with pandemic potential, vector-borne or animal-reservoir viruses with epidemic potential, armed conflict-related threats and chemical, biological, radiological and nuclear ('CBRN') threats, and antimicrobial resistance ('AMR'). 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 the Commission 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.

Activities carried out under this action may include, by way of example: horizon scanning and identification of pathogens with pandemic potential, including through pathogen watch exercises covering emerging biological threats and novel entities of concern; health assessments of identified priority pathogens encompassing transmissibility, pathogenicity, morbidity and burden of disease, including scenario modelling; non-health related assessments of cross-border health threats, including cost-benefit and cost-effectiveness analyses of potential intervention strategies; mapping and analysis of the availability and accessibility of medical countermeasures across vaccine, therapeutic, diagnostic and medical device categories, including supply chain vulnerabilities and pipeline products; and assessments of medical countermeasure gaps and R&D needs, including with respect to pathogen-agnostic and platform technologies.

This action builds on action CP-p-23-14 from the 2023 EU4Health work programme. Synergies with the ECDC and other decentralised agencies will be sought 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)²⁰⁸

Indicative budget for this thematic area: EUR 687 335

Implementation by: HaDEA

CP-p-26-32 Global and EU wastewater sentinel system (DG 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. Cooperation and coordination between competent authorities responsible for public health and competent authorities responsible for urban wastewater treatment is being strengthened, including as per Article 17 of the Directive 2024/3019²⁰⁹, 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 actions CP-p-24-18 and CP-p-25-39 from the 2024 and 2025 EU4Health work programmes and aims to continue supporting the ongoing activities to a global dimension. This action should continue to cover testing of wastewater samples on the request of the Commission and in close collaboration with the ECDC, in strategic sites through e.g., PCR analysis of SARS-CoV-2, PCR analysis of other priority pathogens, next-generation-sequencing measurement and shotgun metagenomics in wastewater sample, measurement of pollutants of concern in 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:

²⁰⁸ HADEA/2024/OP/0009 - Multiple Framework Contracts in cascade for support services to the European Commission on gathering intelligence on priority threats and medical countermeasures.

²⁰⁹ [Directive \(EU\) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment \(recast\) \(Text with EEA relevance\).](#)

- a) building on and cooperating with the joint action on wastewater surveillance EU-WISH²¹⁰ and the global consortium for wastewater and environmental surveillance for public health ('GLOWACON')²¹¹;
- b) operationalising the EU's sentinel system and contributing to a global sentinel system;
- c) supporting cooperation with international stakeholders in a global effort, in line with GLOWACON; and
- d) supporting the coordination at a 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 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), (c), and (j) of Regulation (EU) 2021/522. This action also contributes to the implementation of the Directive (EU) 2024/3019 as well as to the European Water Resilience Strategy²¹².

Indicative type of contracts/supply: use of existing framework contract(s)²¹³

Indicative budget for this thematic area: EUR 8 000 000

Implementation by: HaDEA

CP-p-26-33 Study barriers and enablers for the introduction and adoption of innovative vector control MCMs in the EU market (DG HERA)

In recent years, Europe has faced a growing threat from invasive mosquito species and the diseases they transmit, driven by climate change, increased global travel and trade, and evolving ecological conditions. These developments have increased the need for effective and sustainable vector control measures across the Union. At the same time, the availability of innovative tools and products in the Union market remains limited, with regulatory complexity, fragmented implementation, and commercial disincentives often delaying or discouraging innovation.

This action aims to support a study that will contribute to the Commission's intelligence-gathering functions by analysing current and emerging vector control methods in the Union, alongside factors delaying new medical countermeasures ('MCMs'), including barriers and

²¹⁰ EU-WISH joint action under [the 2023 EU4Health work programme](#) call 'Direct grants to Member States' authorities: to enhance, extend and consolidate wastewater surveillance for public health (HERA)'.

²¹¹ GLOWACON, the Global Consortium for Wastewater and Environmental Surveillance for Public Health, brings together diverse partners from across sectors and countries to share knowledge, expertise, and resources, with the goal of creating a safer and healthier world for all. Its mission is to promote the institutionalization of wastewater and environmental surveillance within public health systems, and to develop a global sentinel system for epidemic outbreaks.

²¹² [COM\(2025\) 280 final](#) - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Water Resilience Strategy.

²¹³ HADEA/2024/OP/0017 - Framework contracts to provide services and supplies to measure pathogens and pollutants of emerging concern in untreated wastewater samples as part of a global sentinel system.

enablers for the introduction and adoption of innovative vector control MCMs in the EU in order to identify and address concrete gaps in the EU's vector control framework and thereby initiate effective countermeasures.

This study aims to identify the barriers and enablers affecting the introduction and uptake of innovative vector control methods and products in the EU market. It will provide a comprehensive overview of the regulatory and market environment governing vector control and contribute to a better understanding of how the EU can support innovation and improve access to such products.

Based on a throughout analysis, the study will include recommendations for possible actions to support innovation, facilitate timely market entry, and ensure that investment is targeted to address concrete gaps in the EU's vector control toolbox, in line with Member State needs and emerging 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 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: open call for tenders or use of existing framework contract(s) for studies and/or research services

Indicative budget for this thematic area: EUR 600 000

Implementation by: HaDEA

CP-p-26-34 Purchase, innovation and deployment of medical countermeasures in emergency situations (DG 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, in case of the development of a serious cross-border health threat or recognised public health emergency, the Commission may reserve capacities for the production and/or purchase and/or deployment of medical countermeasures ('MCMs'). In these cases, the maximum volume to be procured shall be determined by reference to the epidemiological needs of Member States, and/or partners organisations selected by the Commission, while the price per unit or per course of treatment shall be determined based on available market intelligence and prevailing market conditions at the time of procurement. The maximum volume and MCMs pricing shall be subject in all cases to the overall budget ceiling of this action.

Additionally, where MCMs are produced, purchased, and/or deployed, they shall support and/or complement Members States and/or partners organisations selected by the Commission's preparedness and response capacities, and be complementary to actions under the Union Civil Protection Mechanism. Based on the Commission's needs assessment, Member States and/or partners organisations selected by the Commission may then act as MCM buyers or as donation beneficiaries.

Furthermore, this action can also support MCMs intelligence gathering, research and innovation in case of outbreaks and other cross-border health crisis, in synergy with emergency research activities funded under the Horizon Europe Programme. It can include activities such as clinical trials linked to specific countermeasures needed to address the health threat or the performance of specific tests including sequencing in samples to detect a given threat. 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.

This action will also support the provision of adequate logistics and transports services, in complementarity with the Union Civil Protection Mechanism ('UCPM'), 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/or samples for research and development or clinical trials.

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.

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

Indicative type of contracts/supply: use of any type of procurement procedures or existing contracts for the purchase and/or reservation of production and/or supply of relevant medical countermeasures, including their deployment²¹⁴; and/or for intelligence gathering of medical countermeasures.

Indicative budget for this thematic area: no budget allocated. The exact budget for this action will depend on the needs and the specific medical countermeasures to be procured with a ceiling of EUR 70 000 000 within the DG HERA's budget for 2026 as identified in table 3, which already includes EUR 530 873 allocated for the procurement of Favipiravir (antiviral) in response to the 2026 Andes Hantavirus outbreak. Other past examples include a similar emergency procurement action that was performed with a budget of approximately EUR 46 000 000²¹⁵. 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 the Commission in its threat assessment.

²¹⁴ Where applicable, procedures implemented under this action shall preferably comply with the standard liability conditions set in the Commission model contractual terms for supply contracts, unless the contracts' specific nature demands special provisions and/or derogations without which the procurement cannot be implemented. In the latter case, any special provisions and/or derogations shall be discussed with Legal Service and DG Budget as necessary.

²¹⁵ Supply of Modified vaccinia ankara against monkeypox under [the 2022 EU4Health work programme CP-p-22-01.02](#) ('Procurement of vaccines against infectious disease threats such as pandemic influenza (HERA)').

Implementation by: HaDEA/DG HERA

CP-p-26-35 Special Eurobarometer on Antimicrobial Resistance (DG SANTE)

The 2023 Council Recommendation on stepping up EU actions to combat antimicrobial resistance ('AMR') in a One Health approach 2023/C 220/01²¹⁶ complements and builds on the 2017 European One Health Action Plan against AMR²¹⁷, which foresees that the Commission will provide insights into reported public use of and knowledge about antimicrobials through Eurobarometer surveys.

The last Eurobarometer on AMR dates from 2022²¹⁸. It revealed that knowledge about antibiotics is still lacking in the Union with only half of those questioned being aware that antibiotics are ineffective against viruses, and that there are still great differences in Union citizens' awareness across Member States.

There is a need to assess progress in the use of, and knowledge about, antibiotics among the general population.

The aim of this new Eurobarometer on AMR is to monitor progress in the use of, and knowledge about, antibiotics among the general population across EU Member States. It will assess antibiotic consumption among the general public, levels of understanding of how antibiotics work and the risks of their inappropriate use, as well as whether citizens feel sufficiently informed about the need to reduce unnecessary use. In addition, the Eurobarometer will provide insights into public knowledge about the One Health approach and perceptions of the interconnections between human, animal and environmental health in the context of AMR.

The expected outcome is a report analysing the data and progress as compared to previous editions, and factsheets for each EU Member State.

Furthermore, the results of this Eurobarometer edition will give an overview about citizens use and perception of antibiotics in 2026. This will allow to see how the situation has evolved in each Member State as compared to the previous edition in 2022 and can be further used to design tailored educational and/or awareness campaigns for those Member States where more progress might still be needed, and for specific audiences (e.g. citizens and healthcare professionals, among others).

Finally, the results of this Eurobarometer edition will be used for the report to the Council in 2027 on the implementation of the Council Recommendation on AMR.

This action supports the policy priority on EU action on Antimicrobial resistance 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 in order 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, points (b) 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 500 000

Implementation by: HaDEA/DG SANTE

²¹⁶ [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.

²¹⁷ [A European One Health Action Plan against Antimicrobial Resistance.](#)

²¹⁸ [Antimicrobial Resistance - November 2022 - Eurobarometer survey.](#)

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1. ONE HEALTH

DP-p-26-36 Study on the design of an indicator framework for the EU One Health Actions (DG SANTE)

The One Health approach recognises the fundamental interdependence of the health of humans, animals, plants and the environment at large. It is increasingly perceived as crucial for addressing the expanding array of interlinked health threats, including infectious and non-communicable diseases ('NCDs'), antimicrobial resistance ('AMR'), and health effects induced by climate change and other environmental determinants. Contemporary regional and global health challenges, including the spread of avian influenza strains with zoonotic potential, epitomise the need to operationalise and implement the One Health approach, in recognition that these challenges exceed the scope of any single discipline, societal sector or policy area.

One Health is a priority for the Commission, as reflected in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare, which calls for continued action to "build on the One Health approach". Union activities in this domain are informed by the Scientific Advice Mechanism's Opinion on One Health²¹⁹ (2024), which advocated for stronger EU-level One Health governance and greater interdisciplinary collaboration. The Union commitment is mirrored at the global level, where the approach has been institutionalised at major international fora, demonstrated by the establishment of the Quadripartite partnership between World Health Organization ('WHO'), Food and Agriculture Organization ('FAO'), World Organisation for Animal Health ('WOAH'), and UN environment programme ('UNEP').

Recommendation 5.3 of the Scientific Advice Mechanism's Opinion on One Health (2024) provides that the successful implementation of the One Health approach will depend on monitoring and evaluating the initiatives involved, with a clear demonstration of the benefits they bring. This requires the development of appropriate qualitative and quantitative indicators.

The study objective is to develop integrated models and key performance indicators to assess effectiveness of One Health implementation taking account of suitable existing examples of evaluation systems. It should design a robust indicator framework to monitor and evaluate the effectiveness, progress, and impact, including socioeconomic aspects, of One Health actions across human, animal and environmental sectors, in the Union.

The study will seek to answer the following main questions:

- What are the criteria and the indicators that are most useful to assess the effectiveness of the tools and measures and for monitoring the implementation of the One Health approach?; and
- How can the impact of the implementation of the One Health approach be measured?

As result, the indicator framework will enable evidence-based decision-making and enhance the EU's ability to measure progress in One Health implementation and possibly adjust actions.

The One Health approach recognises the central role of the environment in sustaining the health of humans, other animals and plants. In doing so, the approach acknowledges the importance of addressing climate change – given its role in increasing infectious diseases risks and

²¹⁹ [One Health governance in the European Union, Publications Office of the European Union, 2024.](#)

exacerbating NCDs – and of safeguarding biodiversity, which can serve as a natural barrier against zoonotic spillovers. This action contributes to the horizontal policy priority aimed at fighting climate change. It addresses possible environment- and climate-related crises posing a threat to health security.

This action contributes to the achievement of 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 objectives defined in Article 4, points (a), (b) and (i), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 250 000

Implementation by: HaDEA

2.2 TOBACCO CONTROL POLICY

DP-p-26-37 Operation of IT databases under the Tobacco Products Directive (DG SANTE)

The Tobacco Products Directive 2014/40/EU²²⁰ 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 ('EU-CEG')²²¹ product database;
- b) monitoring and oversight of the tobacco tracking and tracing system.

The Commission will continue to provide and develop the EUCEG (designed to reduce administrative burden for companies and regulators and make it easier to compare data) 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 EU-CEG product database and monitoring/oversight of the tobacco tracking and tracing system, allowing for the monitoring of all movements of tobacco products manufactured or imported in the Union, from the manufacturer to the last economic operator, before the first retail outlet.

This action implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (a), 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-26-38 Operation of technical group for characterising flavours under Directive 2014/40/EU (DG SANTE)

The implementation of the Tobacco Products Directive 2014/40/EU 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, roll-your-own tobacco and heated tobacco products.

The general objective of this action 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

²²⁰ OJ L 127, 29.4.2014, ELI: <http://data.europa.eu/eli/dir/2014/40/oj>.

²²¹ [EU Common Entry Gate \(EU-CEG\) - Public Health - European Commission](#).

characterising flavour other than tobacco. To reach these 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 Commission to support decisions and replies to the requests from Member States.

The activity will cover the operation of the procedure for the period 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 at the request of the IAP;
- d) maintenance and further refinement of the methodology.

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

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

Indicative budget for this thematic area: EUR 610 000

Implementation by: HaDEA

2.3 EUROPEAN REFERENCE NETWORKS

DP-p-26-39 Independent assessments and evaluations of European Reference Networks and of Healthcare Providers (DG SANTE)

Commission Implementing Decision 2014/287/EU²²² ('Implementing Decision') sets out criteria for establishing and evaluating European Reference Networks ('ERNs') and their members and for facilitating the exchange of information and expertise on establishing and evaluating those networks.

The Implementing Decision stipulates that each network and healthcare provider applicant, once their eligibility checked, should be technically assessed according to the criteria set out in Delegated Decision 2014/286/EU²²³. The assessment should, based on a common assessment manual, include an exhaustive documentation review and on-site audits of a selected number of applicants. The technical assessment shall be carried out by Independent Assessment and Evaluation Bodies appointed by the Commission.

Implementing Decision (2014/287/EU) determines the process for the assessment, approval and establishment of ERNs.

In addition, according to the Implementing Decision, all Networks and their members must be periodically evaluated, at the latest every five years after their approval or last evaluation, by a body appointed by the Commission.

²²² OJ L 147, 17.5.2014, ELI: http://data.europa.eu/eli/dec_impl/2014/287/oj.

²²³ OJ L 147, 17.5.2014, ELI: http://data.europa.eu/eli/dec_del/2014/286/oj.

This relates to the performance of independent Assessments or Evaluations of ERNs and of Healthcare Providers (HCPs) under Article 12 of Directive 2011/24/EU²²⁴ on patients' rights in cross-border healthcare.

The objectives of the action are:

- evaluation of 24 ERNs and their members by an Independent Assessment and Evaluation Body;
- assessment of new ERNs Networks and HCPs wishing to join the new Networks and/or assessment of new HCPs wishing to join existing Networks.

Expected results:

- evaluation of Networks and Members in accordance with Commission Implementing Decision 2014/287/EU;
- assessment of Networks and HCPs in accordance with Commission Implementing Decision (2014/287/EU) and Implementing Decision (EU) 2019/1269.

Directive 2011/24/EU, which has been incorporated in the EEA Agreement, applies to EU and EEA/EFTA countries. Consequently, centres outside of the EU/EEA cannot join the ERNs or the tools established under the ERN legislation.

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

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

Indicative budget for this thematic area: EUR 2 250 000

Implementation by: HaDEA

DP-p-26-40 Health Policy Platform (DG SANTE)

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 ("Virtual Platform") 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. The aim of the EU Health Policy Platform is to build up good collaboration and communication channels with its health stakeholders.

It is in line with Article 168(2) of the Treaty on the Functioning of the European Union (TFEU)²²⁵ for the Commission 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.

The Virtual Platform is an IT-infrastructure contributing to the exchange of communication between DG SANTE and stakeholders (via the "Agora"), the development of joint statements by stakeholders on specific issues (through temporary "thematic networks"), discussion on

²²⁴ OJ L 88, 4.4.2011, ELI : <http://data.europa.eu/eli/dir/2011/24/oj>.

²²⁵ OJ C 115, 9.5.2008, ELI: http://data.europa.eu/eli/treaty/tfeu_2008/art_168/oj.

selected topics through regular webinars and support the communication of Commission expert and stakeholder groups. 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 contributes to:

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

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: service contract(s) using existing framework contract(s).

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&NCD-p-26-41 Administrative support to the Europe's Beating Cancer Plan's governance mechanism and stakeholder engagement (DG SANTE)

The 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 and quality of life of cancer patients and survivors.

The purpose of this action is to provide additional administrative support to the governance mechanism and stakeholder engagement, information dissemination, including for the governance mechanism of the plan.

The result of the use of support services will be the smooth operation of the governance of the Cancer Plan: Member States, stakeholders and the Interservice Group. The support would ensure that documentation is kept at high level, by producing background documents and also disseminating communication and information material for the groups.

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

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

Indicative budget for this thematic area: EUR 100 000

Implementation by: HaDEA/DG SANTE

CR/CV&NCD-p-26-42 IT support for applications under the Europe's Beating Cancer Plan (DG SANTE)

The Europe's Beating Cancer Plan ('Cancer Plan') aims to reduce the burden of cancer through prevention and improved health literacy, recognising that approximately 40% of cancer cases in the EU can be prevented. By enhancing health literacy and providing accessible, understandable information on cancer prevention, the Plan seeks to reduce cancer-related disparities and promote a healthier population.

The European Code Against Cancer ('Code'), first launched in 1987, provides evidence-based recommendations to help individuals reduce their risk of developing cancer. The 5th edition of the Code has been updated to reflect the latest scientific evidence.

The Cancer Plan aims to make at least 80% of the population aware of the Code by 2025. The dissemination of the 5th edition of the Code is crucial to achieve this goal and to ensure that the latest scientific evidence is translated into action and that the public is aware of the steps they can take to reduce their risk of cancer.

An EU Mobile App for Cancer Prevention has been developed as a tool to disseminate the Code's recommendations to the general public, healthcare professionals, and other stakeholders.

Many of the major risk factors for cancer are also risk factors for other non-communicable diseases (NCDs), such as cardiovascular health. The aforementioned actions thereby support comprehensive approach to health promotion and prevention in line with the Mission letter to the Commissioner for Health and Animal Welfare.

The objective of this action is to support the dissemination of the 5th edition of the Code to the general public, healthcare professionals, and other stakeholders to achieve the goal to make at least 80% of the population aware of the Code.

The specific objectives of this action are to:

- provide continued support and as necessary hosting and maintaining of the app to ensure business continuity, and as needed;
- deliver security plan to align the app with EC corporate governance.

The expected results for the support services are:

- increased awareness of the 5th edition of the European Code Against Cancer among the general public, healthcare professionals, and other stakeholders, with a focus on reduced inequalities in health literacy;
- in the mid-term, a contribution to the achievement of the Europe's Beating Cancer Plan's objective of making 80% of the population aware of the Code;
- in the long-term, a reduction in cancer incidence, as well as improved health outcomes for individuals at high risk of developing cancer, through the promotion of healthy lifestyle choices and the adoption of the Code's recommendations.

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

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

Indicative budget for this thematic area: EUR 148 000

Implementation by: DG SANTE

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

4.1. IMPLEMENTATION OF REGULATION ON HEALTH TECHNOLOGY ASSESSMENT

HS-p-26-43 Supporting joint work of Member States in the field of health technology assessment (DG SANTE)

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment²²⁶ ('the HTA Regulation') applies since 12 January 2025, starting with medicinal products for the treatment of cancer and advanced therapy medicinal products. From 2026, a selection of high-risk medical devices and *in-vitro* diagnostic medical devices are also subject to the joint work.

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

The main thread of the Member States' joint work is conducting joint clinical assessments ('JCAs') and joint scientific consultations ('JSCs').

Article 27 of the HTA Regulation stipulates that the Union shall ensure the financing of the work of the HTACG and its subgroups, including the work on JCAs and JSCs.

The objective of this action is to conduct JCAs and JSCs. The scope and requirements of the joint work are defined by the HTA Regulation. This also includes the systematic involvement of patients, clinical experts, and other experts in the JCA and JSC.

JCAs and JSCs to be funded under this action can be conducted on medicines, medical devices or *in vitro* diagnostic medical devices. The expected number of JCAs and JSCs is included in the 2026 Work Programme of the HTACG²²⁷.

The deliverables are JCA reports and summary reports as well as JSC outcome documents in accordance with the rules set out in the HTA Regulation, its implementing acts and the methodological guidance of the HTACG.

The expected result is the production of JCA reports and summary reports as well as outcome documents for JSCs. 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), (g) and (i), of Regulation (EU) 2021/522.

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

²²⁶ OJ L 458, 22.12.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>.
²²⁷ [HTACG Annual Work Programme 2026](#).

Indicative budget for this thematic area: EUR 10 000 000

Implementation by: HaDEA

HS-p-26-44 Training of patients and clinical experts to participate in joint work under the HTA Regulation (DG SANTE)

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment²²⁸ ('the HTA Regulation') applies since 12 January 2025, starting with medicinal products for the treatment of cancer and advanced therapy medicinal products. From 2026, a selection of high-risk medical devices and in-vitro diagnostic medical devices are also subject to the joint work. The rules will be extended to orphan medicinal products in January 2028 and will, as of 2030, cover all new medicinal products.

The Regulation focuses on clinical aspects of health technology assessment ('HTA') and provides a permanent legal framework for the conduct at Union level of joint clinical assessments ('JCAs'), joint scientific consultations ('JSCs'), the identification of emerging health technologies and joint work on methodologies. It mandates the systematic involvement of patients/carers and clinical experts in joint clinical assessments and joint scientific consultations to ensure that joint work is of the highest scientific quality. The Commission is responsible for identifying these experts.

Patient training programmes were made available under the EU4Health Programme in 2022 (action HS-g-22-20.01/20.02) and ended in 2025. As the HTA Regulation is now in application, there is a need to adapt and boost the training of patients for their involvement in JCAs and JSCs. Training has not yet been provided for clinical experts, and it is paramount that appropriate training is made available for them to participate in the joint work.

The action supports the implementation of the HTA Regulation through training activities, aiming at:

- a) developing and delivering training programmes for patients and clinical experts participating in their individual capacity to JSCs and JCAs;
- b) increasing the number of patients and clinical experts with knowledge of HTA and the HTA Regulation, in particular, their role in JCAs and JSCs;
- c) improving the capacity of patients and clinical experts to provide robust and meaningful input to HTA activities, in particular the JCA and JSCs, including dissemination of the output produced;
- d) increasing the knowledge of patients and clinical experts on the Union HTA legal framework and the understanding of their role when invited to contribute to joint HTA activities for their subject matter expertise and acting in individual capacity;
- e) ensuring the appropriate implementation of the rules with regards to the independence and impartiality of patients and clinical experts involved in joint HTA work;
- f) making information available for patients and clinical experts in Union official languages and exploring artificial intelligence solutions for training delivery.

The action will:

- a) contribute to the appropriate implementation of the rules to ensure the independence and impartiality of patients and clinical experts involved in joint HTA work;

²²⁸

OJ L 458, 22.12.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>.

- b) raise awareness among patient and clinical experts on the new Union legal framework on HTA and stimulate their engagement with HTA bodies at national and Union level, including dissemination of produced output.

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), (g) 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 1 000 000

Implementation by: HaDEA

HS-p-26-45 Continuous development and maintenance of the HTA IT platform (DG SANTE)

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment²²⁹ ('the HTA Regulation') applies since 12 January 2025.

The HTA Regulation provides for the establishment of an IT platform to facilitate the joint work and the secure exchange of information between Member States on health technology assessment ('HTA').

The evolving work on joint clinical assessments ('JCAs') and joint scientific consultations ('JSCs') creates the need for the maintenance and further development of the HTA IT platform which was established under the preparatory phase for the implementation of the regulation. A specific secure space shared only by the HTA Secretariat and the European Medicines Agency ('EMA') has been established for the necessary interchanges of confidential information with the EMA.

The action has the overall objective to ensure that the necessary IT infrastructure and security measures (e.g. website, intranet, databases, secure system for exchanging information) are available, maintained and continuously improved to produce joint work under the HTA Regulation, including JCAs, JSCs, reports on the identification of emerging health technologies, as well as results of other joint voluntary activities agreed by the Member States.

The platform should also facilitate the submission of evidence by health technology developers, the activities for patients and clinical experts contributing to the joint work as well as exchange of information among stakeholder organisations. The platform also provides an interface to submit and assess declarations of interests of persons involved in the joint work. It hosts workspaces for the Member State Coordination Group on HTA and its subgroups.

This action should include exploratory work for the applicability of artificial intelligence solutions in the implementation of the joint clinical assessments under the EU HTA regulation. This should build on any existing work on enabling AI solutions (e.g. linked to European Health Data Space, European Medicines Agency).

The expected results are:

²²⁹ OJ L 458, 22.12.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>.

- a) a one-stop-shop for national HTA experts when preparing, endorsing and accessing JCAs and JSCs reports;
- b) a secure and user-friendly platform for health technology developers when submitting commercially confidential data required for JCAs and JSCs and for patients and clinical experts when providing their input;
- c) interoperability with relevant databases and platforms, and integration of artificial intelligence solutions as appropriate to enhance the efficiency of the joint work. In particular with EMA and its new IRIS system.

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

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

Indicative budget for this thematic area: EUR 2 600 000

Implementation by: DG SANTE

HS-p-26-46 Evaluation of the application of Regulation (EU) 2021/2282 on health technology assessment (DG SANTE)

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment²³⁰ ('the HTA Regulation') applies since 12 January 2025.

Article 31 of the HTA Regulation stipulates that, no later than 13 January 2028, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation.

Moreover, no later than 13 January 2027, Member States shall report to the Commission on the application of the HTA Regulation and, in particular, on the consideration of joint work in their national health technology assessment ('HTA') processes, including the way joint clinical assessment reports have been considered when carrying out national HTAs, and the workload of the Coordination Group. Member States shall also report on whether they have considered methodological guidance developed at Union level for the purpose of national assessments.

The objective of this action is to provide evidence and analysis in the form of a study to support the Commission in drafting the report on the application of the HTA Regulation.

The report shall focus on reviewing:

- a) the added value for Member States of the joint work and, in particular, whether the health technologies subject to joint clinical assessments ('JCAs') and the quality of those JCAs correspond to the needs of Member States;
- b) the non-duplication of the request of information, data, analyses and other evidence for JCAs in terms of reducing the administrative burden for Member States and health technology developers;

²³⁰

OJ L 458, 22.12.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>.

- c) the functioning of the support framework and, in particular, whether there is a need to introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint scientific consultations ('JSCs').

The evaluation shall cover all elements mentioned in Article 31 of the HTA Regulation. Additional elements may be required by the Commission in order to establish a comprehensive picture of the progress in the Member States in using the results of the joint assessments in national decision-making as well as progress in stakeholders' awareness and involvement in the first three years of application.

The study shall provide a set of indicators and gather the necessary qualitative and quantitative evidence from a wide range of relevant stakeholders. This action should also address how to facilitate the collection of information from Member States, in fulfilment of their reporting obligations under Articles 13(2), 14(4), 24 and 31(2), of the HTA Regulation. This action also supports the Commission in conducting the analysis of information listed in Article 31(3) of the HTA Regulation.

As a result of this activity, the study is expected to be used by the Commission to prepare the report requested by Article 31 of the HTA Regulation. This analysis of the application of the HTA Regulation is instrumental to optimise its application and, if appropriate, to present a legislative proposal in order to update that regulation.

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 existing framework contract(s).

Indicative budget for this thematic area: EUR 250 000

Implementation by: HaDEA/DG SANTE

4.2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND PHARMACEUTICAL STRATEGY

HS-p-26-47 Data-driven policy making for medical products (DG SANTE)

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 evidence-based assessments and 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 exercises 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 was set up, which is expected to run until 2028, to support the Commission in its activities related to evidence-based and data-driven policy making. Funding for the above framework contract has been provided also under the 2025 work programme, action HS-p-25-53. This action foresees to continue providing funding for actions, through specific contracts signed under the existing framework contract. It will support the work on the implementation of the Union pharmaceutical legislation, once adopted, which is one of the priorities outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare²³¹.

This action will:

- a) provide impartial economic and market analyses in the area of pharmaceuticals and medical devices. These analyses will support the Commission to enhance the factual foundation of policymaking in the area of pharmaceuticals and medical devices, for example during the implementation of the new Union pharmaceutical legislation, such as during the preparation of secondary and tertiary legislation;
- 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 Europe²³² 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.

²³¹ [Mission letter](#) to Commissioner for Health and Animal Welfare.

²³² 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](#).

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

- a) 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);
- b) 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 aspects related to the health sector, 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(s).

Indicative budget for this thematic area: EUR 1 000 000

Implementation by: HaDEA/DG SANTE

HS-p-26-48 IT support to the European Medicinal Products database (DG SANTE)

The purpose of the European Medicinal Products (EMP) database²³³ is to support the DG SANTE with the creation, maintenance, amendment, suspension, or withdrawal of medicinal products 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 output.

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(s).

Indicative budget for this thematic area: EUR 450 000

Implementation by: DG SANTE

²³³ [Union Register](#) of medicinal products.

HS-p-26-49 Administrative support to events and groups related to the affordability and availability of medicines, including the Critical Medicines Act (DG SANTE)

The Pharmaceutical Strategy for Europe²³⁴ states that the Commission will support the development of cooperation in a group of competent authorities, based on mutual learning on pricing, payment and procurement policies, to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Pharmaceutical Strategy also commits the Commission to continue to work, including through the exchange of best practices, on the uptake of biosimilars, in order to stimulate competition.

Among other activities related to biosimilars, the Commission is therefore organising an annual biosimilar multistakeholder event. The objective of this meeting is to raise awareness towards all and highlight the potential of biosimilars in improving affordability and access to medicines.

To address the growing issue of medicines shortages and improve the security of supply of critical medicines, the Commission adopted a proposal for a Critical Medicines Act²³⁵ (CMA) on 11 March 2025. This proposal aims to increase the resilience of pharmaceutical supply chains and reduce dependencies on a limited number of suppliers or countries for the production of critical medicines and their active substances. It also intends to enhance the availability of other medicines of common interest, such as novel antimicrobials and orphan medicines.

The proposal also proposes the establishment of a Critical Medicines Coordination Group (CMCG), to facilitate the application of the proposed Regulation.

A political agreement on the proposal between the European Parliament and the Council of the European Union was reached on 12 May 2026.

To ensure timely implementation of the CMA once agreed by the co-legislators, preparatory actions would need to be initiated during the transitional period and further actions would be needed to support the implementation.

The objective of this action is to support Member States and stakeholders in contributing to the affordability and availability of medicines. Regarding the CMCG, the objective is also to ensure that the CMA will be operational in a timely manner once it enters into force.

The scope of this action is limited to administrative support on events and groups related to the affordability and availability of medicines, such as:

- a) conference on the adoption of the Critical Medicines Act;
- b) the group of National Competent Authorities on Pricing and Reimbursement (NCAPR);
- c) the yearly Biosimilar Multistakeholder Event;
- d) the Critical Medicines Coordination Group.

Activities to support the organisation of physical, hybrid or online meetings could for instance include secretarial support, logistic support, moderation services, communication and dissemination services.

²³⁴ 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](#).

²³⁵ Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, [COM\(2025\) 102 final](#).

For the proposed CMA:

- a) in the short-term, this action will support the Commission to ensure the timely implementation of the CMA;
- b) in the long-term, this action will contribute to maximising the impact of the measures envisaged by the CMA and therefore is expected to boost the resilience of supply chains for critical medicines and reduce the burden of medicine shortages for patients and society.

For the NCAPR and annual Biosimilar Multistakeholder Event:

- a) in the short term, the expected result is to strengthen the NCAPR members' capacities and to provide them with an improved environment to develop and implement national policy actions, as well as to increase the awareness of stakeholders on the potential of biosimilars;
- b) in the long-term, Member States and stakeholders will be better equipped to make use of their respective capacities towards the Pharmaceutical Strategy's goal, to ultimately improve access to affordable medicines across the Union.

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

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

Indicative budget for this thematic area: EUR 655 000

Implementation by: HaDEA/DG SANTE

HS-p-26-50 Study to assess the impact of supply quota and parallel trade on shortages (DG SANTE)

The Union faces increasing challenges with medicine shortages, posing significant risks to public health and patient care across the Member States. Root causes of shortages are complex and multifaceted, stemming from issues along the entire pharmaceutical value chain. These include quality and manufacturing problems, commercial decisions and distribution issues.

The European Court of Auditors (ECA) published a special report on critical shortages of medicines in September 2025. This report highlights, as part of ECA's recommendations to improve the functioning of the Single Market for medicines, the need to "assess the impact of supply quotas and parallel trade on shortages, and propose appropriate solutions" by the end of 2028.

Parallel trade refers to the practice of exporting medicines from a Member State with lower prices and supplying another Member States with higher prices, using price differentials driven by varying national regulations, market conditions and pricing policies. In the meantime, supply quotas have been established by marketing authorisation holders to define and limit the quantity of medicines they supply to the different Member States, based on the estimated national demand.

Such practices have raised concerns regarding their potential impact on medicines shortages. While supply quota and parallel trade can affect the availability of medicines in certain Member States, it is also often used to prevent or mitigate shortages in others.

To mitigate the risk of medicine shortages, certain Member States have introduced export restriction measures. Such measures can also impact the medicines availability in other Member States that rely on imports of medicines.

The objective of this study is to analyse the impact of supply quota and parallel trade practices on medicines shortages.

The activities under this action could include to:

- a) identify and quantify supply quota and parallel trade practices across the Union and make the link with the different policies of Member States;
- b) survey the concerned stakeholders and collect qualitative and quantitative evidence on the positive and/or negative impacts of such practices on the availability of medicines across the Union;
- c) identify national export restriction measures resulting from parallel trade practices and their impact;
- d) present possible solutions to limit the negative impact of supply quotas and parallel trade on medicines shortages.

On the short-term, this action will contribute to a better understanding and mapping of supply quota and parallel trade practices within the Union and to presenting possible solutions to limit their impact on medicines shortages.

On the medium-term, the results of this study will support future policy actions aiming at reducing shortages and strengthening the availability of medicines across the Union.

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

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

Indicative budget for this thematic area: EUR 300 000

Implementation by: HaDEA

4.3. BIOTECH

HS-p-26-52 Facilitating the implementation of decentralised manufacturing for biotech medicinal products (DG SANTE)

This project is expected to contribute to the objectives of the Commission proposal for a European Biotech Act²³⁶ and the reform of the EU pharmaceutical legislation²³⁷ by enhancing the availability of biotech products to patients. More specifically, the pharmaceutical reform contains a framework for decentralised manufacturing of medicinal products.

Decentralised manufacturing (DCM) enables production of medicinal products closer to the point of care rather than relying exclusively at a central, large-scale manufacturing facility. This approach is particularly relevant for personalised treatments, such as Advanced Therapy Medicinal Products (ATMPs), which often have short-shelf lives or require patient-specific customisation. In these cases, DCM aims to reduce logistical barriers and improve clinical flexibility by allowing facilities to quickly adapt to patient-specific needs and minimise time to administration.

The pharmaceutical reform seeks to establish a robust DCM framework. Ensuring that specific medicinal products are manufactured closer to the patients when justified. This includes maintaining stringent regulatory oversight to ensure product quality and patient safety, therefore prioritising patient benefits alongside regulatory compliance.

Moreover, the project aligns with the Biotech Act proposal's objectives by supporting the market introduction of novel biotech products, providing resources to biotech startups, and ultimately enhancing patient access to transformative medicines.

The project aims to address the challenges to innovation in manufacturing technologies, particularly in the development of breakthrough therapies, to bolster Union competitiveness and support economic growth. This would be achieved through the provision of support to organisations or healthcare centres exploring manufacturing of ATMP at point of care, showcasing the efficacy of the proposed provisions on DCM across Member States.

Projects eligible for funding should focus on biotech innovations, preferably ATMPs, aimed at obtaining approval for decentralised manufacturing or enabling expansion into additional decentralised sites. This will enhance accessibility of the treatment to the patients. Academic institutions, non-for-profit organisations, start-ups and SMEs, public health institutions will be encouraged to apply as they are at the forefront of innovation. The ability to deploy the biotech product in several Member States will be an asset in the project selection process.

The contractor should encompass entities working on the effective implementation of decentralised manufacturing of innovative products in the Union, focusing on the following objectives:

- a) undertake regulatory activities needed for the deploying biotech products in new healthcare centres via decentralised manufacturing;

²³⁶ Proposal for a Regulation of the European Parliament and the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act) [COM/2025/1022 final](#).

²³⁷ [Reform of EU pharmaceutical legislation](#).

- b) request scientific advice and submit regulatory applications for DCM in the Union, when applicable;
- c) provide training and technical support to healthcare professionals within the DCM framework;
- d) if relevant, ask for scientific advice to National Competent Authorities ('NCAs') for the authorisation and supervision of DCM products and sites;
- e) enhance information exchanges with regulatory authorities for authorisation, inspections and regulatory oversight.

Mandatory deliverables:

- a) planned deployment of the biotech products to the patients in several healthcare centres in the Union;
- b) preparation of a comprehensive technical regulatory dossier and submission of an application for decentralised manufacturing of innovative biotech medicinal products such as ATMPs;
- c) development of a report summarising the key steps, lessons learned, and main challenges encountered during the regulatory evaluation and supervision of DCM products and sites, including the registration of decentralised sites; and,
- d) organisation of a conference/closing event to communicate on the lessons learned and good practices collected from the action, with participation of regulatory authorities involved in the concerned project.

By addressing the needs of economic developers and innovators, this initiative is expected to facilitate the adoption of cutting-edge manufacturing technologies. This will ensure the availability of medicines to patients.

Expected results:

- a) enhanced availability of biotech medicinal products for patients in the healthcare centres;
- b) assistance to the developers and manufacturers of innovative medicines in proximity to patients.

Ultimately, this project is expected to contribute to the objectives of the proposed European Biotech Act, enabling developers to bring novel biotech medicinal products to market, and enhancing patient access to transformative medicines.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c), (g) 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 3 000 000

Implementation by: HaDEA

4.4. IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUE AND CELLS AND ORGANS

HS-p-26-53 Development of SoHO digital platform (SoHO-X) (DG SANTE)

Chapter XI of 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 application²³⁸ ('SoHO Regulation') requires the Commission to establish, manage, and maintain a substances of human origin ('SoHO') platform to facilitate exchange of information concerning SoHO activities in the Union in a user-friendly and structured way. This platform will support provisions under different other chapters of the 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 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.

The following are mandatory deliverables:

- 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.

²³⁸ OJ L, 2024/1938, 17.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>.

- 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 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 (c), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 1 500 000

Implementation by: DG SANTE

HS-p-26-54 Supporting joint work of Member States in the field of substances of human origin (DG SANTE)

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 application²³⁹ ('SoHO Regulation') established the SoHO Coordination Board ('SCB') and specifies the delegation of tasks to working groups. Each nominated member and alternate of the SCB and its working groups is a representative of the substances of human origin ('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) of the SoHO Regulation 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 the SoHO Regulation. Different tasks will need to be

²³⁹ OJ L, 2024/1938, 17.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>.

covered, in function of evolving needs and progress in the SCB and its working groups. For example, the following tasks are 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) drafting of opinions on classification of innovative SoHO;
- d) development of best practices, for example:
 - for handling rapid alerts;
 - for implementation of SoHO supervisory activities.

The outcome 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 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 improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (c), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 2 000 000

Implementation by: HaDEA

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

HS-p-26-55 Implementation of EUDAMED (DG SANTE)

The implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices²⁴⁰ and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices²⁴¹ is a key priority for the Commission and the Member States, as highlighted in the mission letter of the Commission President von der Leyen to the Commissioner for Health and Animal Welfare²⁴², the Council Conclusions on the Future of the European Health Union of June 2024²⁴³ and several debates in the Employment, Social Policy, Health and Consumer Affairs Council (the ‘EPSCO Council’).

EUDAMED is one of the core elements of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. EUDAMED enhances transparency, coordination and regulatory oversight. This action will support the finalisation of the IT development, improvement and maintenance of EUDAMED, as well as its translation needs. 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. EUDAMED is structured around six interconnected modules: Actors registration, UDI/Devices registration, Notified Bodies and Certificates, clinical investigations and performance studies, post-market surveillance and vigilance, market surveillance - with the first three already available for voluntary use. EUDAMED is now in an advanced stage of development, and this action is supporting the finalisation and maintenance of the first five modules and the continuation of development of the sixth.

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

The action will contribute to the development and maintenance of and translations necessary for the EUDAMED database, by:

- a) supporting the finalisation and maintenance of the post-market surveillance and vigilance module, including for the post audit phase and the readiness of the module for its mandatory use;
- b) supporting the development of the last module, clinical investigations and performance studies, for which a number of challenges have been identified, requiring appropriate technical solutions;
- c) supporting the independent audit of the post-market surveillance and vigilance and the clinical investigations and performance studies module;

²⁴⁰ OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

²⁴¹ OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

²⁴² [Mission letter](#) to Commissioner for Health and Animal Welfare.

²⁴³ [Council Conclusions](#) on the Future of the European Health Union of June 2024.

- d) supporting the onboarding of the users in view of the mandatory use of the modules declared functional;
- e) supporting the development of remaining functional specifications and enhancements to be developed on the four modules (Actors, UDI/Devices, NBs & Certificates and Market surveillance) after EUDAMED minimum viable product delivery for which the notice of functionality was published, including those to be delivered before their mandatory use and further changes, also taking into account possible legislative developments;
- f) supporting the translations of user interface, user guides, documentation and onboarding material.

This action supports transparency for patients and healthcare professionals as well as traceability of devices placed in the Union market. EUDAMED, the first Union comprehensive database for medical devices, will enhance market surveillance and collaboration of Member States to support the sustainability of their health systems and accordingly supports safer healthcare. Thousands of Union and non-EU operators will provide data on an expected volume of 5 million devices placed on the Union market in a single European database, avoiding duplication of registration at national level.

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: open call for service contract or negotiated procedure for service contract.

Indicative budget for this thematic area: EUR 7 665 000

Implementation by: HaDEA/DG SANTE

HS-p-26-56 Support to the technical secretariat of the Notified Body Coordination Group (DG SANTE)

The implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices²⁴⁴ and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices²⁴⁵ 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 Welfare²⁴⁶, the Council Conclusions on the Future of the European Health Union of June 2024²⁴⁷ and several debates in the Employment, Social Policy, Health and Consumer Affairs Council configuration (the 'EPSCO Council').

This action aims at ensuring smooth implementation of sectorial legislation. The Commission provides support to the activities of the Notified Body Coordination Group (NBCG-Med)²⁴⁸

²⁴⁴ OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

²⁴⁵ OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

²⁴⁶ [Mission letter](#) to Commissioner for Health and Animal Welfare.

²⁴⁷ [Council Conclusions](#) on the Future of the European Health Union of June 2024.

²⁴⁸ [Notified Body Coordination Group](#) (NBCG-Med).

established under Article 49, of Regulation (EU) 2017/745 and Article 45, of Regulation (EU) 2017/746. Considering the challenges that notified bodies are facing in the implementation of the regulatory framework for medical devices and *in vitro* diagnostic medical devices, strengthening such support is essential to contribute to smooth implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

This action aims to improve the capacity of notified bodies in delivering essential technical documentation necessary for smooth implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

This action has the objectives to:

- a) support the NBCG-Med technical secretariat to help the drafting of technical documents for the implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, in coordination with authorities responsible for notified bodies and/or national competent authorities;
- b) support coordination among authorities responsible for notified bodies and the notified bodies to carry out specific activities necessary for the implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, in synergy with the Medical Device Coordination Group Notified Bodies Oversight Working Group²⁴⁹.

Activities under this action will consist in providing services to NBCG-Med and assisting the Chairpersons of the NBCG-Med in carrying out technical related duties in coordination with national authorities within the Medical Device Coordination Group Notified Bodies Oversight Working Group. Specific tasks include the coordination and scientific support to the NBCG-Med and its subgroups, the preparation and follow up of meetings, and communication activities.

By supporting the coordination among notified bodies, this action will ensure enhanced harmonisation and predictability of the certification process. Ultimately, this will support the simplification efforts of the Commission resulting in burden reduction for both national competent authorities and economic operators.

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 new framework contract.

Indicative budget for this thematic area: EUR 400 000

Implementation by: HaDEA

²⁴⁹ Medical Device Coordination Group [Notified Bodies Oversight Working Group](#).

HS-p-26-57 Study on methodologies for regulatory sandboxes for medical devices and *in vitro* diagnostic medical devices (DG SANTE)

The revision²⁵⁰ of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices²⁵¹ and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices²⁵² is a key priority for the Commission and the Member States, as highlighted by the Commissioner for Health and Animal Welfare during his public hearing at the European Parliament²⁵³ upon his appointment and as reiterated by Member States' representatives in the context²⁵⁴ of the Competent Authorities for Medical Devices (CAMD). Moreover, in the Council Conclusions on the Future of the European Health Union of June 2024²⁵⁵ and several debates in the Employment, Social Policy, Health and Consumer Affairs Council (the 'EPSCO Council'), Member States also stressed the importance of supporting innovation and fostering the development and availability of innovative and affordable devices in the Union.

This action aims at complementing the Commission's revision proposal of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 adopted in December 2025 and at ensuring a common methodology throughout the Union for using regulatory sandboxes in the sector of medical devices, which are key tools to support faster placement of innovative devices on the Union market, and to create opportunities for tailored advice to developers/manufacturers.

The study objectives are to:

- a) analyse existing and planned national or sectoral approaches to regulatory sandboxes in health and other relevant sectors;
- b) identify best practices, challenges, and success factors for effective implementation of sandboxes;
- c) develop a common methodological framework and practical guidance for the design, operation, and evaluation of medical device sandboxes under Regulation (EU) 2017/745 and Regulation (EU) 2017/746²⁵⁶;
- d) facilitate cooperation and knowledge-sharing among competent authorities, notified bodies, and innovators.

The mandatory deliverables will include:

- a) comprehensive report mapping existing sandbox practices and lessons learned;
- b) draft and final version of a common union methodology for regulatory sandboxes in the medical devices sector;

²⁵⁰ Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, [COM/2025/1023 final](#).

²⁵¹ OJ L 117, 5.5.2017, p. 1-175, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

²⁵² OJ L 117, 5.5.2017, p. 176-332, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

²⁵³ [Hearing of Olivér Várhelyi](#), Commissioner-designate (Health and Animal Welfare).

²⁵⁴ Competent Authorities for Medical Devices [consensus statement](#) "Coordination and governance of the regulatory system for medical devices at the EU level".

²⁵⁵ [Council Conclusions](#) on the Future of the European Health Union of June 2024.

²⁵⁶ Aiming for synergies as appropriate with the AI Act regulatory sandboxes.

- c) recommendations for the Member States and the Commission on setting up of regulatory sandboxes in the medical devices sector;
- d) mock-up of practical cases undergoing assessment under a regulatory sandboxes;
- e) final stakeholder workshop to present and validate outcomes and propose follow-up actions.

This study will support innovation in the Union medical devices sector and will foster the competitiveness of the medical technologies sector, while also contributing to the Union simplification efforts by allowing more flexibility and providing for an innovation-friendly regulatory environment. This action complements the Commission's revision proposal of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, adopted in December 2025 and aimed at making the current rules for medical devices easier, faster and more effective, to promote competitiveness, innovation and a high-level of patient safety in this key sector.

In the short term, this action is expected to deliver a shared understanding and evidence base on how regulatory sandboxes can be effectively used in the medical devices sector. It will map national experiences, identify best practices, and establish a common Union methodology for the design and operation of such sandboxes under Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

The resulting framework is expected to provide practical guidance for the Commission, competent authorities, notified bodies, and innovators, promoting a coherent and proportionate approach to testing innovative technologies in real-world settings.

In the midterm, the action is expected to enhance the predictability and efficiency of regulatory interactions for manufacturers. It will support regulatory learning and evidence generation in a controlled environment, ultimately reducing barriers to innovation while maintaining high safety and performance standards.

At Union level, the action will strengthen cooperation and trust among regulatory actors, encourage cross-border collaboration, and contribute to the Union's strategic autonomy and global leadership in medical technology innovation.

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 (c) 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 700 000

Implementation by: HaDEA

4.6. IMPLEMENTATION OF CROSS-BORDER HEALTHCARE DIRECTIVE

HS-p-26-58 Study assessing the Member States' operation of the Directive 2011/24/EU and other Union legislation relating to patient mobility (DG SANTE)

Article 20 of Directive 2011/24/EU²⁵⁷ established an obligation for the Commission to periodically report to the European Parliament and to the Council on the operation of the Directive. The next report is due in 2027.

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.

The main objective is to assess the systems and practices put in place in the Member States and EEA countries to implement Directive 2011/24/EU and implementing Directive 2012/52/EU²⁵⁸. This assessment should regard the:

- patient flows
- financial dimensions of patient mobility
- implementation of Article 7 and Article 8 of the Directive 2011/24/EU
- functioning of the European Reference Networks
- functioning of the National Contact Points
- mutual recognition of prescriptions (Article 11(1) of Directive 2011/24/EU and implementing Directive 2012/52/EU).

This action will result in a comprehensive report assessing the implementation of Directive 2011/24/EU in EU Member States and EEA countries.

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 objectives defined in Article 4, points (g), (h) and (i), of Regulation (EU) 2021/522.

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

Indicative budget for this thematic area: EUR 300 000

Implementation by: HaDEA/DG SANTE

4.7. HEALTH PROFESSIONALS

HS-p-26-59 Programme of Continuous Learning within a European Health Union Professional Network (Health Union Fellowship Programme) (DG SANTE)

The Union already benefits from diverse stakeholders active in capacity-building for health policy development and implementation in Europe, delivering high-quality training and professional education. These capacity-building entities target a range of policy-relevant expertise and include specialised training programmes such as health law, health economics,

²⁵⁷ OJ L 88, 4.4.2011, ELI: <http://data.europa.eu/eli/dir/2011/24/oj>. Current consolidated version: ELI: <http://data.europa.eu/eli/dir/2011/24/2025-01-12>.

²⁵⁸ OJ L 356, 22.12.2012, ELI: http://data.europa.eu/eli/dir_impl/2012/52/oj.

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.

Since 2024, two cohorts of mid-career professionals from Member States Ministries of Health or other relevant administrations have been enrolled in a one-year training programme. The 2026/2027 cohort will consist of tentatively 34 fellows and will include representatives of EU4Health associated countries (Norway, Iceland, Ukraine, Moldova, Montenegro, Bosnia and Herzegovina, and Serbia).

The network of professionals will not only include the cohort of participants, but also the graduated alumni, their mentors, training facilitators and stakeholders, a permanent and growing community that collaborates and contributes to build a stronger European Health Union.

Activities will include face-to-face and online technical training modules on Union public health policies, exchange of practices, case studies, opportunities to connect and network with a diverse set of experts and stakeholders, an annual conference.

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 existing framework contract(s).

Indicative budget for this thematic area: EUR 1 400 000

Implementation by: HaDEA

4.8. GLOBAL HEALTH

HS-p-26-60 Development and maintenance of the EU Global Health Strategy monitoring framework (DG SANTE)

The EU has established itself as a global health leader, a role that was reinforced during the COVID-19 pandemic. Building on this experience, the EU adopted the EU Global Health

Strategy²⁵⁹ in 2022, which provides a comprehensive framework for addressing global health challenges in a coordinated manner. Building on the EU GHS, the Global Health Resilience Initiative was released in May 2026, setting out the **strategic framework for future EU action** so that Europe can respond quicker to health threats and crises in an interconnected world.

As part of the implementation of the two strategies, developing a dashboard key performance indicators to monitor progress of the identified global health actions is essential to increase the visibility of EU contributions, enhance coordination, and strengthen the EU's leadership. Such a database will help to showcase the collective impact of EU efforts in advancing global health.

The objective of this action is to further develop and maintain an online database that presents key indicators to monitor the implementation of the global health strategy and the flagships initiatives of the Commission Communication on global health resilience across different EU funding programmes. The scope includes improving and updating the existing database and online tool created under the contract HS p-23-71-02 "*Operationalise methodology for mapping Union health policy actions and financing streams and develop metrics to assess implementation of the global health strategy*"²⁶⁰. The tool would be further complemented with the results of the Joint Action on Global Health Impact²⁶¹.

Activities will include the provision of technical services to maintain and update the internal database and the online publicly accessible tool.

The expected results will be to have an operational dashboard showcasing EU's global health actions in one single publicly accessible platform. This will improve access to information, coordination and visibility of the Union actions. Furthermore, the dashboard will strengthen transparency and accountability by showing how EU funding supports the implementation of the Global Health Strategy and the Global Health Resilience Communication. It will also help identify synergies, avoid overlaps, and support decision-making.

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 objectives defined in Article 4, points (a), (f) and (j), of Regulation (EU) 2021/522.

Indicative type of contracts/supply: amendment of an existing service contract, expert contracts with fees following establishment of/under existing call for expression of interest, including membership/subscription fees.

Indicative budget for this thematic area: EUR 100 000

Implementation by: HaDEA/DG SANTE in collaboration with DG INTPA

²⁵⁹ [EU Global Health Strategy.](#)

²⁶⁰ [2023 EU4Health Work Programme - Public Health - European Commission.](#)

²⁶¹ [EU Global Health Impact.](#)

5. DIGITAL (DI)

DI-p-26-61 Health Data IT portal and Secure Processing Environment Operational Setup for multi-country application requests (DG SANTE)

Regulation (EU) 2025/327 of the European Parliament and of the Council ('EHDS Regulation')²⁶² provides for the establishment of a digital infrastructure (HealthData@EU) to facilitate the re-use of electronic health data for secondary uses.

Under Article 75(9) of the EHDS Regulation, when requested by two or more national contact points for secondary use, the Commission may provide a secure processing environment ('EC SPE') compliant with the requirements of Article 73 for data from more than one Member State. Furthermore, under Article 96(1), points (e) and (g), of the EHDS Regulation, concerning the roles and responsibilities of the Commission in the functioning of the EHDS, the Commission shall develop, maintain, host and operate the infrastructures and central services required to support the functioning of the EHDS for all relevant connected entities. This includes services to submit health data access applications to electronic health data held across several Member States or other authorised participants in HealthData@EU, and to automatically forward these applications to the relevant contact points. Additionally, the Commission shall develop, maintain, host and operate an EC SPE in which Health Data Access Bodies ('HDABs') can decide to make data available.

The present action focuses on testing and validating the developments of the central services, mentioned above, with the creation of the Health Data IT portal which would function as a receiver HDAB. The aim is to ensure that these services can be fully operational by the time of entry into application of the key provisions of the EHDS Regulation, as foreseen in the legislation. This action is expected to establish and operationalise the EC SPE as a service to Member States for multi-country data access application requests.

The objective of this action is to support the operational setup and expansion of capabilities for both the Health Data IT Portal and the EC SPE. This will enhance the interoperability and efficiency of health data exchange across the Commission and Member States, ultimately improving healthcare delivery and policy-making.

The scope of this action covers the setting up and scaling-up of essential digital business capabilities for the Health Data IT Portal and EC SPE:

Health Data IT Portal: is developed to mimic a national HDABs to test and validate the central services provided to the national HDABs by the EU central platform of the HealthData@EU infrastructure. The Health Data IT Portal shall have the below functions:

- a) dataset catalogue management: publish and update catalogues of metadata record describing datasets held by EUIBs;
- b) data access application: assess, decide and issue permits for secondary use of health data through transparent criteria, including the management system to record, process and streamline applications;
- c) digital gateway: connect with other HDABs, authorised participants and the EU central platform of the HealthData@EU infrastructure for secondary uses of health data;
- d) secure data provision: ensure access via secure processing environments, in pseudonymised/ anonymised formats;

²⁶²

OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

- e) data quality labelling: apply and oversee quality/utility labels on datasets;
- f) coordinate and ensure data preparation of the datasets according to the issued permit;
- g) coordination & harmonisation: collaborate with HDABs and federate national catalogues through HealthData@EU;
- h) opt-out management: operate a system allowing natural persons to opt out from secondary use;
- i) transparency & reporting: publicly disclose permit decisions, access application requests and the results of the studies performed with data accessed through the Health Data IT Portal.

EC SPE: functionally equivalent to Member States' Secure Processing Environments, ensuring health data is processed in a secure and compliant manner. The EC SPE will provide a secure environment where health data from more than one Member State, an authorised participant and/or from EU-level bodies can be processed according to EHDS requirements.

The activities to be carried out as part of this action for 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) development and testing;
- d) deployment and operations;
- e) provision of reference implementations;
- f) other preparatory or support actions and capacity building at the Commission (e.g. studies).

Through this action is expected to have both a Health Data IT Portal and an EC SPE as mandated by the EHDS Regulation, operational by the legal deadline, March 2029, as stipulated in the Regulation.

The expected impact of this action is a more efficient secondary use of health data for purposes such as research, innovation, personalised medicine, policy-making, official statistics, patient safety and regulatory activities, while ensuring a common approach, as set out in the EHDS Regulation.

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

Indicative type of contracts/supply: open call / negotiated procedure for the launch of new contract(s), and/or other procurement procedures, use of existing framework contract(s), administrative arrangements, co-delegations with other DGs.

Indicative budget for this thematic area: EUR 5 500 000

Implementation by: DG SANTE

DI-p-26-62 Analytical studies supporting the implementation of the European Health Data Space Regulation (DG SANTE)

Regulation (EU) 2025/327 of the European Parliament and of the Council²⁶³ (‘EHDS Regulation’) establishes a comprehensive framework for the primary and secondary use of health data in the Union. Its implementation requires the adoption of several implementing acts and the establishment of Union-level infrastructures and services, notably HealthData@EU. In line with the Better Regulation principles, proportionate analytical support may be needed to prepare these measures. Such studies will provide evidence on costs, impacts and feasibility of different options, ensuring that the implementing acts and related measures are effective, proportionate and legally sound. This action will allow the Commission to target studies that underpin the preparation of implementing acts and other implementation measures under the EHDS, thereby supporting Member States and stakeholders in the rollout of the EHDS Regulation.

The scope includes targeted studies on issues such as dataset descriptions, secure processing environments, interoperability requirements, or reporting and transparency tools.

The main activities will include:

- a) data collection;
- b) cost-benefit analysis;
- c) mapping of national practices; and
- d) and formulation of policy options.

The main deliverables will be study reports, containing evidence-based recommendations, that will feed directly into the Commission’s preparation of implementing acts and other measures. These studies are expected to be launched within 2026 to ensure timely input for the legislative and implementation process.

The studies are expected to provide robust and proportionate evidence to inform the preparation of EHDS implementing acts and measures. In the short term, they are expected to enable the Commission to prepare legally and technically sound measures, reducing the risk of challenge and ensuring coherence with Better Regulation requirements. In the medium term, the studies are expected to contribute to a smoother rollout of the EHDS by clarifying requirements for data holders, Member States and infrastructures, while minimising unnecessary administrative burden. Overall, the action intends to increase legal certainty, stakeholder trust and efficiency of EHDS implementation.

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

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

Indicative budget for this thematic area: EUR 500 000

Implementation by: HaDEA/DG SANTE

²⁶³ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

DI-p-26-63 Studies supporting the European Health Data Space progress reports (Article 102(4) Regulation (EU) 2025/327) (DG SANTE)

Article 102(4) of Regulation (EU) 2025/327 of the European Parliament and of the Council²⁶⁴ ('EHDS Regulation') requires the Commission to prepare annual progress reports following 25 March 2025. These reports will cover both the primary use of health data (interoperability of Electronic Health Records ('EHRs'), certification, internal market, etc.) and the secondary use of health data (opt-out, permitted uses, data access).

To ensure robust, timely and comparable reporting, the Commission needs to establish a structured reporting framework, building on existing capacity building actions and on Member State's contributions. Such reporting framework will define common indicators, methodologies and data collection procedures.

The action will therefore cover both the design phase (analysis, methodology, piloting) and the implementation phase (data collection, synthesis, reporting), and is aimed at minimising the administrative burden of the reporting process. This will guarantee that the Commission delivers robust, evidence-based progress reports and that reporting feeds back into EHDS governance and policy adjustments.

This action has a dual objective:

- a) design a coherent reporting framework for Article 102(4) obligations, covering both primary and secondary use;
- b) apply the reporting framework to collect information from Member States and stakeholders and prepare input for the first annual progress reports.

The main activities include:

- a) legal and technical mapping of Article 102(4) of the EHDS Regulation reporting requirements;
- b) development of indicators and templates for Member States, stakeholders and EU-level data collection;
- c) piloting of the reporting framework;
- d) full-scale data collection and input delivery that will feed into the first progress report under Article 102(4);
- e) synthesis of results, ensuring consistency with the EHDS governance and capacity building actions.

The mandatory deliverables of this initiative are:

- a) reporting framework and tested methodology;
- b) input to the first Commission progress report (Article 102(4)), based on collected data;
- c) recommendations for the targeted evaluation due in 2033 (Article 102(1)) and overall evaluation of the EHDS Regulation due in 2035 (Article 102(2)).

In the short term, the action is expected to provide the Commission with a structured, operational methodology for fulfilling its reporting obligations under Article 102(4) of the EHDS Regulation. This intends to improve coherence across primary and secondary use of health data, establish clear indicators and ensure comparability of results between Member

²⁶⁴ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

States. In the medium term, the action is expected to deliver input to the progress reports (Article 102(4)) of the EHDS Regulation that will provide the Council with robust evidence on the progress in implementing the EHDS. The outputs are also expected to strengthen policy feedback loops, support the development of implementing acts and inform future investments under EU4Health and Digital Europe.

Overall, the action intends to enhance transparency, accountability and trust in the EHDS, while reducing duplication and administrative burden for Member States through harmonised reporting.

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

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

Indicative budget for this thematic area: EUR 600 000

Implementation by: HaDEA

DI-p-26-64 Development, deployment and operations of the MyHealth@EU central services on primary uses of health data (DG SANTE)

MyHealth@EU, formerly known as eHealth Digital Service Infrastructure or eHDSI, was established under the Cross-Border Healthcare Directive (2011/24/EU)²⁶⁵ as an EU-level infrastructure for the exchange of health data with voluntary participation of Member States. MyHealth@EU is now included in the scope of Regulation (EU) 2025/327 of the European Parliament and of the Council²⁶⁶ ('EHDS Regulation').

This infrastructure enables Member States authorities to exchange health data in a secure, efficient and interoperable way. As a result, MyHealth@EU services enable people/individuals to benefit from healthcare in the country of travel within the Union in the same way that they benefit in their country of residence.

As of early 2025, 16 Member States are connected. More Member States are in the process of onboarding. Under Article 23 of the EHDS Regulation, Member States are required to connect to MyHealth@EU by 2029.

Two services are currently operational, ePrescriptions/eDispensations and Patient Summaries, which will become mandatory by March 2029. Both services aim to convey and translate the respective information they contain into the language applicable in the country of treatment. The expansion of MyHealth@EU to new services for medical imaging studies and related imaging reports, medical test results, including laboratory and other diagnostic results and related reports, and discharge reports is required by the EHDS Regulation by March 2031. The Commission provides central services for this infrastructure as foreseen in Article 23 and Article 96 of the EHDS Regulation.

The objective of this action is to support the development, maintenance and operation of the central services by the Commission for MyHealth@EU under the current eHealth Network framework and the new framework under the EHDS Regulation.

²⁶⁵ [Electronic cross-border health services - European Commission \(europa.eu\)](https://european-council.europa.eu/media/e300042c-325c-4f30-b0f8-9020a52d9138/default.aspx?lang=en).

²⁶⁶ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

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 any upgrades or updates required by the European Health Data Space.

The main activities to be carried out as part of this action include:

- a) analysis, design and development;
- b) piloting and testing, including automation of testing and other activities;
- c) deployment and operations;
- d) other actions included in the work plan of MyHealth@EU and
- e) 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.

As a result of this action, the Commission services are expected to be able to continue to support the operations of MyHealth@EU as well as Member States' participation as foreseen in the current framework under the Cross-border healthcare directive.

This action is expected to support the transition to the EHDS and the services required by the EHDS Regulation. It also intends to support full rollout of the infrastructure geographically and with the necessary services portfolio within the EHDS.

This action implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (f) 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 3 000 000

Implementation by: DG SANTE

DI-p-26-65 Development and operation of HealthData@EU central services and of the EU database and digital testing environments for Electronic Health Record systems (DG SANTE)

Regulation (EU) 2025/327 of the European Parliament and of the Council²⁶⁷ ('EHDS Regulation') establishes two key obligations on the Commission:

- a) the development and operation of the HealthData@EU central services to enable the functioning of the cross-border infrastructure for secondary use of health data;
- b) the establishment of the EU database for registration of Electronic Health Record ('EHR') systems and wellness applications (Articles 39, Article 47 and Article 49 of the EHDS Regulation) and the provision of software for European digital testing environments for harmonised components of EHR systems (Article 40 of the EHDS Regulation).

Both actions are essential to reduce fragmentation, ensure interoperability, support regulatory implementation, and enable a seamless and secure cross-border exchange and secondary use of health data across the Union.

²⁶⁷ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

The objective of this action is to develop, deploy and operate two of the core EU-level digital infrastructures foreseen in the EHDS:

- a) HealthData@EU central services: design, development, testing, deployment and operations (e.g. EU dataset catalogue federation, application management, routing and monitoring services);
- b) EHR systems & digital testing environments: development, maintenance and operation of the EU database for EHR systems and wellness apps, as well as provision of software for digital testing environments for harmonised EHR components.

The scope covers analysis and design, piloting and testing, deployment and operations, as well as preparatory or support actions (studies, technical support, stakeholder engagement and technical coordination with Member States).

This action is expected to result in:

- a) fully operational HealthData@EU central services supporting the rollout of the secondary use infrastructure;
- b) operational EU database for EHR systems and wellness apps, enabling transparency and enforcement of conformity/label obligations;
- c) availability of open-source software for digital testing environments, supporting harmonised EHR components and facilitating secure data exchange across Member States;
- d) increased interoperability, reduced market fragmentation, and improved trust in the EHDS framework.

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

Indicative type of contracts/supply: open call / negotiated procedure for the launch of new contract(s), and/or other procurement procedures, use of existing framework contract(s), administrative arrangements, co-delegations with JRC, DG RTD, DG DIGIT, DG COMM and DG DGT.

Indicative budget for this thematic area: EUR 5 500 000

Implementation by: HaDEA/DG SANTE

DI-p-26-66 Supporting the maintenance of the European Electronic Health Record exchange Format and common specifications for Electronic Health Record systems (DG SANTE)

Regulation (EU) 2025/327 of the European Parliament and of the Council²⁶⁸ ('EHDS Regulation') establishes the European Electronic Health Record exchange Format ('EEHRxF') as a key element to ensure the secure, interoperable, and consistent exchange of electronic health data across the Union. The EEHRxF and the common specifications for Electronic Health Record ('EHR') systems require continuous maintenance and evolution to reflect updates in medical knowledge, health informatics standards and technological developments.

²⁶⁸ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

To ensure the long-term sustainability and alignment of these specifications with European and international standardisation efforts, support is needed for the coordination, versioning, documentation and stakeholder engagement processes underpinning their maintenance.

The objective of this action is to support the continued maintenance, governance and controlled evolution of the EEHRxF and the common specifications for EHR systems, in line with the EHDS Regulation. The action aims to ensure that these common instruments remain operational, coherent and accessible to Member States and EHR system implementers for both national and cross-border exchange of electronic health data.

The action will cover activities necessary to maintain, update, and manage the artefacts, documentation and tools underpinning the EEHRxF and the related specifications. This may include:

- a) technical and organisational support for version management, documentation and publication of the Format and its components;
- b) coordination and facilitation of expert and stakeholder engagement to assess, review and validate proposed updates;
- c) preparation and maintenance of supporting materials, such as implementation guidance, testing artefacts and reference examples;
- d) monitoring and analysis of relevant developments in standardisation and health informatics to ensure continued alignment with international work;
- e) support for activities related to interoperability testing, conformance and uptake of the specifications by Member States and market actors.

This action is expected to contribute to ensuring the continuity and sustainability of the EEHRxF and the common specifications for EHR systems, as key enablers of interoperable and secure exchange of electronic health data across the Union. It should build on and take into account the results of previous projects in this area co-funded by the Union under the EU4Health and Digital Europe programmes.

In the short term, the action is expected to provide a structured process and resources for maintaining and updating the EEHRxF and related artefacts, ensuring that they remain coherent, usable, and aligned with evolving standards and policy needs.

In the medium term, the action is expected to improve consistency and interoperability of electronic health record systems across Member States, enhance transparency and stakeholder engagement in the maintenance process, and promote alignment with relevant international standards and implementation guides.

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

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

Indicative budget for this thematic area: EUR 5 000 000

Implementation by: HaDEA/DG SANTE

DI-p-26-67 Compliance checks for the European Health Data Space – secondary use (DG SANTE)

Under Article 75(12), Chapter IV for secondary use, of Regulation (EU) 2025/327 of the European Parliament and of the Council²⁶⁹ ('EHDS Regulation') the Commission is obliged to set out the conditions and compliance checks required to be able to join and remain connected to HealthData@EU. Additionally, under Article 96 (1), point (h), of the EHDS Regulation on the roles and responsibilities of the Commission regarding the functioning of the EHDS, the Commission is to develop, maintain, host and operate the infrastructures and central services required to support the functioning of the EHDS, for all relevant connected entities, by means of, among others, compliance checks for connecting authorised participants to HealthData@EU.

The compliance checks framework itself is currently being developed through a separate project, the action DI-p-24-74.2 from the EU4Health 2024 work programme. This action should enable the Commission to conduct the actual compliance checks once the framework is in place for the Member States' national contact points to connect to the HealthData@EU infrastructure by the time the key provisions of the EHDS Regulation enter into application.

The objective of this action is to conduct the actual compliance checks of the national contact points and other authorised participants for their connections to HealthData@EU infrastructure, in particular to verify that they comply with the legal, organisational, technical and security requirements for the secondary use of EHDS.

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 verify compliance of the Member States' national contact points and other authorised participants with their obligations under Chapter IV for secondary use of the EHDS Regulation for the purpose of their connection to the HealthData@EU infrastructure.

The compliance checks are expected to identify findings that may pose risks to confidentiality, integrity or availability of services provided. This intends to increase the trust of participants and other stakeholders in these infrastructures and in the EHDS as a whole.

The participants in these compliance checks, National Contact Points for secondary use and other authorised participants, may use the outcomes of the compliance checks as input to the applications to start or continue/improve the provision of cross-border services.

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

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

Indicative budget for this thematic area: EUR 2 200 000

Implementation by: HaDEA

²⁶⁹ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

6. RECURRENT, HORIZONTAL, IT AND COMMUNICATION ACTIVITIES

The actions have as objectives the organisation of events and meetings, covering expert expenses, including special indemnities, in particular in relation to participation in steering groups, peer reviews 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.

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 2026 will focus on key political priorities.

Moreover, in accordance with Article 26 of Regulation (EU) 2021/522 and as announced in the Communication to the Commission on 'Corporate Communication action in 2024-2027 under the Multi-annual Financial Framework 2021-2027', the corporate communication of the Union's political priorities to the extent that they are related to the objectives referred to in Articles 3 and 4 Regulation (EU) 2021/522 will be supported.

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) 2017/745²⁷⁰ and Regulation (EU) 2017/746²⁷¹, and other Union legislation on health and policies related.

In addition, these actions cover the supporting services for Information Systems for Health, carrying out activities relating to IT Governance and Strategy including chargeback services; 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 Knowledge Online on European Legislation ('KOEL') and its replacement by the acquis management tool ('AMT'), the contribution to the development of the European Crisis Management Platform ('ECMP') including the support to DG SANTE for the follow-up of the Early Warning and Response System development and its connection to the ECMP, 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 and potential candidates 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.

²⁷⁰ OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>. Current consolidated version ELI: <http://data.europa.eu/eli/reg/2017/745/2026-01-01>.

²⁷¹ OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>. Current consolidated version ELI: <http://data.europa.eu/eli/reg/2017/746/2025-01-10>.

Under this heading, a new framework contract to support services for expert groups and other stakeholders in the field of Health and Food will be launched.

These actions also cover support for studies and expert support on challenges and priorities in health and food safety policies, such as supporting legislation development (e.g. impact assessments), its assessment (e.g. evaluations) its implementation and simplification.

These actions also cover expert legal support for the development and implementation of Union health policies.

These actions implement the EU4Health Programme's overall objective of improving 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 indicative actions are, amongst others:

- a) **for events, meetings, and peer reviews:** reimbursement of fees and costs;
- b) **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
- c) **for IT:** provision of corporate technical services;
- d) **for translations:** provision of translation services;
- 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 candidates. 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 Expert Groups:** a new framework contract will be established;
- g) **for experts, data acquisition, legal analyses and studies:** expertise and technical assistance and support in the field of health and food safety policies, applied research and analytical works (for instance in the field of biodefence), exploratory studies, evidence gathering, data acquisition, 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;

Within this thematic area, the Commission plans to launch open procedures for a new framework contract for services related to the expert groups and other stakeholders in the field of Health and Food with a ceiling of EUR 20 million.

Indicative type of contracts/supply: e.g. service contract based on existing framework contracts, open procedures or competitive procedures with negotiation or competitive dialogue procedure, administrative arrangements, co-delegation with other DGs, e.g. DG COMM, DG DIGIT and DG DGT.

Indicative budget for this thematic area: EUR 15 725 831

Implementation by: DG SANTE/DG HERA/HaDEA

C. OTHER ACTIONS AND EXPENDITURE

In 2026, the Commission intends to launch the following actions which contribute to one or several strands.

DP-o-26-68 Technical implementation of the Tobacco Products Directive (DG SANTE)

Tobacco Products Directive 2014/40/EU ('TPD') lays down among others a number of provisions concerning the ingredients and emissions of tobacco products and related products including also safety and quality requirements for nicotine-containing e-cigarettes. It requires prior notification tobacco and related products and prohibits cigarettes, roll-your-own tobacco and heated tobacco products with characterising flavours (e.g., menthol). A need for further technical and scientific input for the implementation of the TPD has been jointly identified by the relevant services of DG SANTE and JRC as the basis for continuation of the mutual administrative arrangement in this area.

This action should further support the application of the TPD and monitoring through technical expertise and laboratory capacity (in particular to analyse the ingredients of tobacco products and e-cigarettes) of the JRC. The research requirements for these products include determining their composition and nicotine content, emissions, and assessing whether they contain particular ingredients such as flavouring substances.

The JRC provides DG SANTE with expert technical support for the potential revision of the TPD and Tobacco Advertising Directive 2003/33/EC²⁷², the characterisation of novel tobacco products and electronic cigarettes, and the design and implementation of analytical methods for priority substances. Through its laboratory capabilities and established networks, the JRC strengthens the European network of tobacco control laboratories, facilitates knowledge exchange, ensures consistent TPD enforcement, and represents the Commission in European and international standardisation and WHO-related activities. Additionally, the JRC offers rapid ad-hoc technical support on emerging products, providing evidence-based data and laboratory analyses to inform policymaking.

This action implements the EU4Health Programme's general objective of strengthening health systems (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: Administrative arrangement with JRC

Indicative budget for this thematic area: EUR 300 000

Implementation by: DG SANTE

²⁷² OJ L 152, 20.6.2003, p. 16, ELI: <http://data.europa.eu/eli/dir/2003/33/oj> Current consolidated version
ELI: <http://data.europa.eu/eli/dir/2003/33/2003-06-20>.

DP-o-26-69 Scientific Committees, functioning of experts' groups, meetings and technical assistance (DG SANTE)

The Scientific Committees on Consumer Safety ²⁷³(‘SCCS’) and on Health, Environmental and Emerging Risks (‘SCHEER’)²⁷⁴ 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.

Committees have been set up by Commission Decision 2024/1514/EC²⁷⁵.

Through this action the Commission will receive:

- 1) scientific opinions (mandated by the Commission services and published, web-activities, monthly expert group meetings, plenary meetings, technical support)
- 2) assistance to the Communication team (e-newsletter) and Health Policy Platform meetings
- 3) networks of experts (IT tools, web page, public consultations, public hearings, calls for experts, working meetings, thematic workshops).

It is expected to:

- a) 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;
- b) review and evaluate available relevant scientific data to derive conclusions and assessing potential risks. Scientific opinions of the Committees 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 contracts with fees following establishment of/under existing call for expression of interest, including membership/subscription fees expert fees.

Indicative budget for this thematic area: EUR 710 000

Implementation by: DG SANTE

²⁷³ [Scientific Committee on Consumer Safety \(SCCS\) - Public Health.](#)

²⁷⁴ [Scientific Committee on Health, Environmental and Emerging Risks \(SCHEER\) - Public Health.](#)

²⁷⁵ OJ L, 2024/1514, 31.5.2024, ELI: <http://data.europa.eu/eli/dec/2024/1514/oj>.

MEMBERSHIP FEES TO INTERNATIONAL ORGANISATIONS AND REGULATORY BODIES

HS-o-26-70 Reimbursements for national experts participating in Commission audits/controls on pharmaceuticals (DG SANTE)

Article 111b(1) of Directive 2001/83/EC²⁷⁶ stipulates that at the request of a third country, the Commission shall assess whether that country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union. Ultimately, the process should lead to the inclusion in the list of third countries considering equivalent in this respect.

The above-mentioned assessment shall include an on-site review (i.e. audit) of the third country's regulatory system taking in particular an account of Good Manufacturing Practices ('GMP') aspects (national rules, inspections to verify compliance and the effectiveness of enforcement). In addition, the Commission shall verify (i.e. audit) regularly that the conditions that led to whitelisting continue to be fulfilled.

At the same time, the Commission may want to confirm, in the context of Mutual Recognition Agreements ('MRAs') for pharmaceuticals, and by means of audits, that third countries with such agreements maintain the capability, capacity and procedures to carry out GMP inspections and enforce compliance.

Moreover, the Commission may need to carry out fact-finding visits (i.e. controls) to enlargement countries to gather information about their regulatory compliance programme on GMP and Good Distribution Practices ('GDP'), in order to have an informed opinion on their preparedness for accession in relation to this area of the Union acquis.

All the above audits and controls, which are a legal obligation or a political priority, are of highly specialised nature, necessitating the participation of national experts with the adequate expertise in order to ensure that the assessment is fit for purpose.

This action aims at supporting the participation of national experts with expertise in the area of GMP/GDP is the corresponding Commission audits/controls.

This action aims at ensuring that the Commission lists third countries as equivalent only if they have a regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that of the Union. The operational result would be an audit report, and the impact would be the listing of the third country (and its retention on the list).

In addition, the action aims at allowing the Commission to confirm that third countries availing of MRAs for pharmaceuticals maintain the capability, capacity and procedures to carry out GMP inspections and enforce compliance. The operational result would be an audit report, and the impact would be to trigger an informed dialogue with the concerned third countries, potentially leading to the adjustment of MRAs.

Moreover, this action aims at allowing the Commission to gather information about enlargement countries regulatory compliance programme on GMP and GDP, in order to have an updated picture of their state of preparedness for accession in relation to these areas of the

²⁷⁶ OJ L 311, 28.11.2001, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>. Current consolidated version <http://data.europa.eu/eli/dir/2001/83/2025-01-01>.

Union acquis. The operational result would be a fact-finding study report, and the impact would be informing the corresponding accession process.

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

Indicative type of contracts/supply: Reimbursement of experts

Indicative budget for this thematic area: EUR 40 000

Implementation by: DG SANTE

HS-o-26-71 Securing Union technical expertise in international fora to secure technical convergence and reliance (DG SANTE)

Following the EU Chairmanship of the International Medical Device Regulatory Forum ('IMDRF') in 2023, it is essential that representatives of national competent authorities of the Member States continue to actively engage and contribute to the IMDRF and its workstreams to represent the Union's interests in this field. Given the observer status of the Union within the Medical Devices Single Audit Programme ('MDSAP'), it is essential to ensure that representatives of national competent authorities of the Member States actively engage in its workstream to fulfil the Union obligations in view of its status. This action will support international harmonisation and reliance on the Union regulatory framework and, ultimately, burden reduction for both national competent authorities and economic operators.

This action aims at supporting the representation of Union delegates in international fora, such as the International Medical Device Regulatory Forum (IMDRF) and the Medical Devices Single Audit Programme (MDSAP) and participation in their relevant work items.

Moreover, this actions also aims at expanding knowledge and expertise of Member States experts in IMDRF technical working groups and MDSAP procedures to facilitate the implementation and transition to relevant requirements in view of the legal proposals for amendments of Union legal framework Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices²⁷⁷ and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices²⁷⁸.

This action seeks to secure that Union technical expertise is provided in international technical discussions to influence and steer international convergence initiatives and facilitate reliance of global partners on the Union regulatory framework.

The expected results and impact are:

- a) increased influence of the Union medical device sector in the global context and increase reliance on the Union framework from other jurisdictions;
- b) active and coordinated participation in meetings and in reliance programmes.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, medical devices, and crisis

²⁷⁷ OJ L 117, 5.5.2017, p. 1-175, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

²⁷⁸ OJ L 117, 5.5.2017, p. 176-332, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (h) and (j), 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-26-72 Joint assessment of notified bodies (DG SANTE)

The implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices²⁷⁹ and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices²⁸⁰ is a key priority for the Commission and the Member States, as highlighted in the mission letter of the Commission President von der Leyen to the Commissioner for Health and Animal Welfare²⁸¹, the Council Conclusions on the Future of the European Health Union of June 2024²⁸² and several debates in the Employment, Social Policy, Health and Consumer Affairs Council (the ‘EPSCO Council’).

Joint assessments are a legal obligation under these Regulations. A joint assessment is carried out by the designating authority together with a joint assessment team composed by Commission experts/auditors and, at least, two national experts. An on-site assessment is part of the overall assessment process for a conformity assessment body being designated as a notified body. For these notified bodies, an on-site assessment is also part of their overall re-assessment, which must be regularly conducted, and of the assessment process for extending their scope of designation.

This action aims at ensuring that only appropriately resourced and adequately performing notified bodies are, and remain, designated and notified. It will support the availability of experts participating in joint assessment teams (which is a legal obligation), notably regarding their on-site component, as well as the training of these experts in order to ensure that such a participation is fit for purpose.

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

Indicative type of contracts/supply: Reimbursement of experts

Indicative budget for this thematic area: EUR 140 000

Implementation by: DG SANTE

²⁷⁹ OJ L 117, 5.5.2017, p. 1-175, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

²⁸⁰ OJ L 117, 5.5.2017, p. 176-332, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

²⁸¹ [Mission letter](#) to Commissioner for Health and Animal Welfare.

²⁸² [Council Conclusions](#) on the Future of the European Health Union of June 2024.

HS-o-26-73 Annual contribution to the International Pharmaceutical Regulators Programme (IPRP) (DG SANTE)

The International Pharmaceutical Regulators Programme ('IPRP')²⁸³ 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 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") biannual meetings.

In line with the Pharmaceutical Strategy for Europe²⁸⁴, 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 Union 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.

As a Member of IPRP, the Commission, represented by DG SANTE, can fully participate in the decision-making, represent, and promote Union policy interests²⁸⁵. Moreover, from a policy standpoint, participation to IPRP provides the opportunity to continue being engaged on a regular basis in a multilateral dialogue on technical and scientific matters with other regulatory authorities.

The funding covers the annual contribution to IPRP paid via ICH (which constitutes a legal entity) that through its permanent secretariat provides the administrative and technical support to IPRP on the basis of a Memorandum of Understanding between ICH and IPRP.

In line with the Pharmaceutical Strategy for Europe and the EU Global Health Strategy²⁸⁶, the expected results and impact are:

- a) ensuring a strong voice globally in international pharmaceutical fora, promoting regulatory convergence and harmonisation to ensure access to safe, effective, high-quality and affordable medicinal products globally;
- b) enhancing international regulatory cooperation and where possible convergence;
- c) fostering greater convergence and stronger alignment with international standards as a core aspect of international cooperation for the improvement of health systems.

This annually recurring action covers the annual contribution to IPRP, 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), (f) and (j), of Regulation (EU) 2021/522.

Indicative budget for this thematic area: EUR 31 000

Implementation by: DG SANTE under other activities (membership-contribution)

²⁸³ [IPRP – International Pharmaceutical Regulators Programme.](#)

²⁸⁴ 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](#).

²⁸⁵ 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.

²⁸⁶ [The EU Global Health Strategy.](#)

HS-o-26-74 Annual membership fee to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and participation of experts from Member States in ICH meetings (DG SANTE)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ('ICH')²⁸⁷ 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). There are over 70 ICH guidelines that the regulatory members of ICH are expected to implement.

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 Europe²⁸⁸, to ensure a strong voice globally in international pharmaceutical fora, promote international regulatory cooperation and when possible convergence and harmonisation to ensure access to safe, effective, high-quality and affordable medicinal products globally, 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 these authorisations is an essential aspect of the implementation of the legislation on medicinal products. The ICH guidelines thus complement Union legislation and policy in the field of pharmaceuticals and contribute to the protection of public health.

These international harmonised ICH guidelines representing high standards facilitate the development of medicinal products, bringing them to markets faster and maintaining them on the markets, thus contributing to availability of medicines globally. Moreover, harmonised requirements facilitate collaboration between regulators, promote reliance and contribute to regulatory convergence.

As a Founding Regulatory Member of ICH, the Commission, represented by DG SANTE, can fully participate in the decision-making in the ICH Association, represent and promote Union policy interests when defining its priorities, e.g. in the selection of new topics for harmonisation, the financing and the work programme²⁸⁹. Moreover, from a policy standpoint, participation in

²⁸⁷ [ICH Official web site: ICH.](#)

²⁸⁸ 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](#).

²⁸⁹ 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.

ICH provides the opportunity to continue being engaged on a regular basis in a multilateral dialogue on technical and scientific matters with other regulatory authorities, industry and any other public and private sector organisations that participate in the ICH Association.

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

Indicative budget for this thematic area: EUR 569 000

Implementation by: DG SANTE

HS-o-26-75 Annual contribution to the European Observatory on Health Systems and Policies Partnership (DG SANTE)

The Observatory is a partnership that brings together different policy perspectives to identify what health systems and policies evidence Europe's decision makers need. The Observatory was created in 1998 and the Commission joined in 2009.

The Observatory has as core functions country monitoring, analysis, performance assessment and knowledge brokering.

Supporting dynamic health systems and new technologies is a key objective of the Union. The Observatory has as one of its aims consists in fostering a health information and knowledge system to contribute to evidence-based decision making.

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

The expected results are:

- Availability of evidence on health systems performance.
- Availability of analysis of different aspects of health systems reforms.
- Ad hoc briefings provided timely on topics of interest for the Union on health systems.
- Availability of a network of professionals working on health systems in the Union.
- Driving the work on health systems in the European region.

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

Indicative budget for this thematic area: EUR 700 000

Implementation by: DG SANTE

D. ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT

In 2026, 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-CO-26-76 Support of innovative medical countermeasures with thematic innovation financial products by the European Investment Bank under the Invest EU Programme (DG HERA)

POLICY CONTEXT

In 2023, the Commission launched the HERA Invest²⁹⁰ initiative, with the aim to help bridge funding gaps and stimulate innovation in health emergency preparedness and response across Europe by supporting EU/EEA SMEs developing innovative MCMs responding to either of the Commission-identified priority threats.

Furthermore, in July 2025, the Commission published its Medical Countermeasures Strategy, outlining key planned actions to support the supply chains of MCMs end-to-end, from research and development to market implementation and procurement. As a main initiative, DG HERA Invest's budget is set to double by 2027, increasing from EUR 100 million at its launch in 2023. This action will offer additional opportunities for innovative EU SMEs to secure the essential funding and facilitate the development of relevant MCMs, enhancing the EUs preparedness and response capabilities in times of crises.

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. Retroactivity is justified to ensure the timely mobilisation of HERA Invest and avoid delays in the implementation of critical preparedness and response activities. 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 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), point (a)(iii), of the STEP Regulation and meets the condition under Article 2(2), point (a).

OBJECTIVES, SCOPE AND ACTIVITIES

With this action, the Commission will further contribute to the Thematic Innovation - Research, Innovation and Digitalisation Window ('RIDW') financial product (more specifically, in the

²⁹⁰ HERA INVEST contribution agreement under [the 2023 EU4Health work programme](#) call CP-CO-23-09 ('Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the InvestEU Fund (HERA)').

policy area ‘1.1 Health innovation investment’) implemented by the European Investment Bank (‘EIB’) under the Invest EU programme. The 2026 action set at EUR 20 million is an addition to the initial Invest-EU allocations of EUR 100 million under the 2023 EU4Health work programme, EUR 10 million under the EU4Health 2024 Work Programme and EUR 20 million under the EU4Health 2025 Work Programme²⁹¹.

The aim of the action is to further support investments into R&D of medical countermeasures for pandemic preparedness, in particular into vaccines and other preventive interventions, therapeutics (including critical medicines), and diagnostics, as mentioned in the guarantee agreement between the EIB and the Commission. This also includes innovative, sustainable and flexible manufacturing projects supporting the extension of manufacturing capacity and the rapid scale-up of production capacity in times of crisis, ensuring ultimately improvement of the availability and access to critical medical countermeasures for cross-border threats to health. The funds will be managed by DG GROW and implemented by EIB. DG HERA will cooperate with DG GROW and EIB for the successful implementation of the action.

The aim of the action is to further support investments, through venture loans, into innovative European companies developing interventions (i.e., diagnostics, therapeutics, vaccines) against priority cross-border health threats (i.e., pathogens with high pandemic potential, AMR, CBRN). Currently, a market failure in the development of such interventions exists in the form of a lack of private investment due to the high-risk nature of such investments (i.e., low probability of success, low expected revenue). This action will provide support in the form of an additional guarantee that will further reduce the risk for potential investors, thereby incentivising private investment, and contributing to the R&D pipeline of medical countermeasures against serious cross-border health threats.

The HERA Invest initiative provides a unique opportunity to alleviate this market failure and provide European autonomy in the development of lifesaving medical countermeasures. The successful support of 3 EU SMEs in 2024/2025 along with the positive feedback from the beneficiaries highlights the important impact of this initiative and advocates for its continuance.

Thanks to the extension of this action, a number of additional medical countermeasures in development responding to priority health threats identified under the Commission’s prioritisation activities will be funded. Therefore, in order to ensure a better understanding of the extent to which market failures support 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. In 2026, a top-up of EUR 30 million will be added to the original amounts of EUR 100 million in 2023, EUR 10 million in 2024 and EUR 20 million in 2025, in the form of a financial instrument. This will contribute to the Thematic Innovation financial product, enabling the EIB to increase their volume of venture loans into specific areas as described above and attract 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 control and

²⁹¹ [C\(2025\) 5148 final](#).

ownership via the Invest EU eligibility checklist procedure, as well as inclusion of third parties. The action aims at attracting third party investors through co-investment, for example from Member States, international donors and private investors. The action promotes innovation and development of new medical countermeasures and will create positive spillovers for international partners.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative budget
CP-CO-26-76	Q4/2026	EUR 20 000 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG GROW	EIB

CP-CA-26-77 Support to the global wastewater surveillance sentinel system (DG HERA)

POLICY CONTEXT

Wastewater surveillance has proven to be a valuable and complementary tool for early detection of infectious disease outbreaks and monitoring community-level health trends. It supports cost-effective and scalable monitoring of pathogens, providing early warnings that guide diagnostic testing, outbreak control, and public health measures.

In 2024–2025, Latin America and the Caribbean have faced increasing public health challenges, including ongoing circulation of arboviruses (dengue, Zika, chikungunya) in the context of climate-related environmental changes. The region’s heterogeneity in surveillance infrastructure, coupled with high urban density and sanitation challenges, underscores the need to strengthen environmental and wastewater surveillance capacities. Strengthening such systems globally is also crucial for Europe, as infectious disease threats know no borders and enhanced surveillance capacity in partner regions contributes directly to the EU’s ability to anticipate, prepare for, and respond to emerging health threats that could impact its own citizens. This is particularly important for the EU’s outermost regions, which often serve as the first points of contact for pathogens circulating internationally. Bolstering surveillance and response capacities in these territories not only protects their populations but also reinforces the EU’s overall early-warning architecture.

This action contributes to the global consortium for wastewater and environmental surveillance consortium for public health (‘GLOWACON’) and aligns with the Commission’s priorities for strengthening global preparedness and response to cross-border health threats. It supports the establishment of a global sentinel wastewater surveillance system by advancing technical capacity and data integration in Latin America and the Caribbean.

The Pan American Health Organization (‘PAHO’), as the specialised health agency of the Inter-American System and WHO’s Regional Office for the Americas, is uniquely positioned to lead this action. PAHO coordinates regional disease surveillance networks, laboratories, and data systems across 35 Member States. Its expertise and regional mandate make it the most

appropriate implementing partner to build on existing health security frameworks and ensure alignment with global and EU-funded efforts, being the most suitable beneficiary for this action, in accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522.

This action directly contributes to the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness and coordination of health systems (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

This action aims to:

- a) strengthen wastewater surveillance systems in Latin America and the Caribbean as part of the global sentinel network for early detection of infectious disease threats;
- b) develop regional technical guidance and capacity-building programmes for wastewater surveillance laboratories and bioinformatics in Latin America and the Caribbean;
- c) promote harmonisation of methodologies, data sharing, and integration into regional health surveillance platforms;
- d) enhance regional preparedness and contribute to global early warning systems that can detect and contain emerging health threats before they reach the EU.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

- a) advancement of wastewater surveillance as an integral tool for pandemic preparedness and response;
- b) enhanced regional capacity for wastewater surveillance, including laboratory, genomic, and data analytic capabilities;
- c) strengthened coordination among national and regional laboratories through PAHO's leadership;
- d) improved detection and monitoring of priority pathogens in wastewater; and
- e) increased availability of harmonised regional guidance and data to inform risk assessment and public health decision-making.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-26-77	Q4/2026	EUR 2 000 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG HERA	PAHO

CP-CA-26-78 Support EMA for the shelf-life extension programme (DG HERA)

POLICY CONTEXT

Medicines in stockpiles are often discarded at expiry, even if still effective. Shelf-life extension ('SLE') of selected MCMs is one possible strategy to enhance stocks sustainability, reduce waste, and optimise stockpile management, while also ensuring that the MCMs still meet applicable standards. In a structured SLE programme MCMs can remain usable beyond their original expiration date, provided they undergo appropriate scientific testing and regulatory oversight.

Based on a pilot study currently being conducted by the Commission, in cooperation with DG ECHO and EMA, and on existing experiences in Member States, this action will aim to establish a shelf-life pilot programme for post hoc SLE for selected MCMs. The pilot programme is focussing on a limited number of rescEU MCMs as an initial test-of-concept before a possible rolling out into a wider programme applicable to more MCMs in the rescEU stockpiles.

The EMA is the appropriate agency for a shelf-life extension programme as it holds the scientific expertise for pharmaceutical quality assessment through its Quality Working Party ('QWP') and Biologics Working Party ('BWP'), works with the Medicines Control Laboratories Network ('OMCL') laboratory network coordinated by the European Directorate for the Quality of Medicines and HealthCare ('EDQM'), maintains the regulatory dossiers for centrally authorised products, and has established relationships with national competent authorities who would implement SLE recommendations through national exemptions under Article 5(2) of Directive 2001/83/EC. By selecting EMA as the beneficiary, this action ensures complementarity between the Commission policymaking activities and EMA independent, scientific expertise. Therefore, EMA is most suitable beneficiary for this action, in accordance with Articles 7(1) and 13(1), point (b), 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 be better prepared to respond to serious cross-border health threats. It contributes to the achievement of the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and improve 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 (b), (c) and (d), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to roll out a full SLE programme for MCMs in rescEU stockpiles, building on the methodology and findings established through the 2025/2026 SLE pilot. Specifically, this action will:

- Apply the validated SLE assessment framework developed during the pilot to additional medicinal products in rescEU stockpiles, prioritising products approaching expiry and likely those with high replacement costs;
- Commission stability testing for selected products, likely through the OMCL network, generating scientific data to support SLE recommendations by quality experts;

- Issue EU-level scientific opinions on SLE that Member States can use as a basis for national exemption decisions under Article 5(2) of Directive 2001/83/EC²⁹² or equivalent national provisions;
- Establish routine processes for SLE assessment including standardised testing protocols, reporting templates, and coordination mechanisms between the Commission, EMA, EDQM, and Member State stockholders.

EXPECTED RESULTS AND IMPACT

In the short to medium term, this action is expected to:

- Reduce wastage of medicinal MCMs and improve the cost-effectiveness and sustainability of EU stockpiles;
- Maintain readiness of strategic stockpiles by ensuring MCMs remain available for deployment over longer periods without compromising quality or safety;
- Strengthen EU-level coordination and scientific consistency in shelf-life extension practices across Member States; and,

Generate an evidence base on MCMs stability that informs future stockpiling, sustainability planning, and policy development.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-26-78	Q4/2026	EUR 500 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG HERA	EMA

CP-CA-26-79 Supporting the development of medical countermeasures against antimicrobial resistance to strengthen global preparedness and response – 2nd phase (DG HERA)

POLICY CONTEXT

Antimicrobial resistance (‘AMR’) remains one of the EU’s highest-priority threats, as identified in the Health Threat Prioritisation 2026 Assessment for Medical Countermeasures⁶. Despite its critical importance, the market for AMR medical countermeasures, particularly new antimicrobials, continues to be affected by significant structural failures. High development costs, together with high failure rates during clinical development and the stewardship requirements necessary to ensure responsible antimicrobial use, have significantly limited private investment. To safeguard a resilient European Health Union, it is therefore essential to ensure the maintenance of a continuous and robust pipeline of AMR medical countermeasures, in order to ensure the availability of a comprehensive set of tools (including vaccines,

²⁹² [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.](#)

diagnostics, and novel antimicrobials and alternative approaches) to support preparedness and response.

Building on the support provided under the 2025 EU4Health Work Programme²⁹³, HERA will continue to partner with Kreditanstalt für Wiederaufbau ('KfW') to coordinate support for innovative AMR medical countermeasures, ensuring synergies across activities and a holistic approach to innovation investments. Through this action, DG HERA expects to expand the number of activities and/or innovative MCMs supported by KfW's agreements with the Global Antibiotic Research and Development Partnership ('GARDP') and/or the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator ('CARB-X'). As this action is expected to reinforce the existing contribution agreement, KfW, with their extensive experience in managing international funding programmes and fostering public-private partnerships to accelerate access of MCMs in the Union and globally, remains the most suitable beneficiary for this action, in accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522

A sustainable response to AMR requires not only investment in late-stage research and development, but also a substantial increase in the number of candidates entering the development pipeline. The development of antimicrobials is characterised by high failure rates, particularly during the transition from preclinical to clinical stages. The World Health Organization's '*Analysis of antibacterial agents in clinical and preclinical development: overview and analysis 2025*'²⁹⁴ confirms that the current global pipeline remains insufficient to address the most critical drug-resistant pathogens, with only a limited number of innovative candidates in development and persistent gaps in essential formulations and technologies. Reliance on a small number of candidates therefore poses a strategic risk to Union preparedness. Accordingly, this action seeks to provide reinforced funding to support a broader portfolio of candidate products. The action will be implemented in complementarity with ongoing support under Horizon Europe and other relevant Union instruments, ensuring coherence across programmes while avoiding duplication of funding. By supporting multiple innovative approaches, it aims to increase the likelihood that effective medical countermeasures to address AMR ultimately reach the market.

This action is consistent with the 2023 Council Recommendation on stepping up EU actions to combat AMR through a One Health approach²⁹⁵ and with the 2024 Political Declaration of the United Nations High-level Meeting on AMR²⁹⁶.

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:

²⁹³ Action CP-CA-25-79 ('Supporting the development of medical countermeasures against antimicrobial resistance to strengthen global preparedness and response (HERA)') ([C\(2025\) 5148 final](#)).

²⁹⁴ [Analysis of antibacterial agents in clinical and preclinical development: overview and analysis 2025](#).

²⁹⁵ [2023/C 220/01](#)

²⁹⁶ [UN Resolution A/RES/79/2](#)

- a) Mitigate R&D risk and ensure pipeline continuity to provide uninterrupted push funding for promising products transitioning from early-stage acceleration to late-stage clinical development.
- b) Enhance health protection within the EU to ensure that the expanded pipeline of AMR medical countermeasures results in products that are accessible and tailored to the EU priority health threats.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

- Enhanced health preparedness and resilience reducing the burden of AMR-related morbidity and mortality;
- An increased development and innovation of AMR medical countermeasures addressing market failures in the field; and,
- Increased availability of new AMR medical countermeasures on the market.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-26-79	Q4/2026	EUR 15 000 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG HERA	KfW

CP-CA-26-80 Support the creation of a Secretariat for the Global Therapeutics Development Coalition (DG HERA)

POLICY CONTEXT

Therapeutics are a critical pillar of public health emergency preparedness and response, alongside vaccines and diagnostics by reducing morbidity and mortality, alleviating health system burden, and providing treatment options when vaccines are unavailable, delayed, or insufficiently effective.

Despite their importance, significant gaps persist. Investment in therapeutics R&D remains fragmented and insufficient, particularly for pathogens with endemic, epidemic and pandemic potential. The current pipeline is thin, poorly coordinated across stages of development, and weakly linked to clinical trial readiness, regulatory pathways, manufacturing capacity, and access planning. As a result, even when promising therapeutics emerge, availability and equitable access are often delayed, in particular for low-and-middle-income countries.

Addressing these gaps requires sustained, coordinated, end-to-end approaches to therapeutics development, with equity considerations embedded from early research through to delivery. Strengthening global coordination is therefore essential to ensure that safe, effective, and accessible therapeutics can be developed and made available rapidly in future health

emergencies, in line with global preparedness objectives such as those highlighted in the IPPS 100 Days Mission²⁹⁷.

This action will contribute to the establishment of the Global Therapeutics Development Coalition ('Global TxDC'), a public-private partnership network designed to facilitate and accelerate the development of therapeutics for priority epidemic and pandemic and endemic threats, with a particular focus on broad-spectrum antivirals across high-risk viral families identified under the WHO R&D Blueprint.

This coalition will be founded by a consortium consisting of IPPS, Unitaid, DNDi, and potentially other stakeholders. From these, Unitaid has a proven track record in supporting end-to-end product development and market-shaping activities for therapeutics, including antivirals, and in embedding access considerations from early research and development through delivery. Through its long-standing experience in leveraging public-private partnerships and collaborating with governments, international organisations, product developers, civil society, and implementers, Unitaid is ideally positioned to launch this new initiative. It is therefore the most suitable beneficiary for this action, in accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522.

Where a contribution agreement cannot be concluded with the implementing partner identified above, the Commission may select different pillar-assessed partner(s) in accordance with the applicable rules. The selection shall take into account criteria including comparable experience and track record in implementing actions of a similar nature and scale; existing contractual or partnership frameworks with the Commission; and/or prior working experience with the Commission in the area(s) covered by this action.

This action supports the implementation of the EU Medical Countermeasures Strategy. The Global Therapeutics Development Coalition is expected to operate in synergy with existing and future Commission initiatives on therapeutics, including the European Therapeutics Hub, thereby reinforcing coherence between EU-level actions and global efforts. In particular, the Therapeutics Development Coalition should align closely with complementary global initiatives, including the WHO R&D Blueprint, as well as the i-MCM-Net²⁹⁸ focusing on product-development gaps between early research and scalable products. Unitaid's (and other partners) strong relationships with WHO, together with its established connections to the i-MCM-Net, will help ensure coherence across efforts.

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 contributes to the 'Flagship initiative 4. Strengthen response capacity through the availability of medical countermeasures' of the Global Health Resilience Initiative²⁹⁹ as well as 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 improve availability, accessibility and affordability of medicinal products, medical devices, and crisis relevant products (Article 3, point (b), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b), (c) and (j), of Regulation (EU) 2021/522.

²⁹⁷ [IPPS](#).

²⁹⁸ Interim Medical Countermeasures Network ([i-MCM-Net](#)).

²⁹⁹ [COM\(2026\) 197 final](#) - Communication from the Commission to the European Parliament and the Council: Reinforcing global health resilience amidst geopolitical change.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to support the establishment of a Secretariat for the Global Therapeutics Development Coalition, enabling the foundational governance, coordination, and stakeholder engagement functions necessary for the coalition to become operational. This action covers the initial phase of the Secretariat's functioning; further operational activities will be considered subject to assessment of progress and the mobilisation of additional funding from other partners.

Specifically, this action will contribute to the following objectives:

- a) set up a functional and independent secretariat to support the governance, coordination, and day-to-day operations of the Global Therapeutics Development Coalition;
- b) facilitate coordination among key global stakeholders across the therapeutics value chain, including public funders, international organisations, R&D initiatives, developers, and civil society, to reduce fragmentation and duplication;
- c) support strategic prioritisation and pipeline analysis visibility for therapeutics targeting pandemic-prone pathogens, in alignment with WHO R&D Blueprint priorities and the 100 Days Mission;
- d) promote early integration of equitable access considerations along the value chain of therapeutics development; and,
- e) promote mobilisation of sustained and coordinated investment in end-to-end therapeutics development.

EXPECTED RESULTS AND IMPACT

This action is expected to:

- a) establish a lean, functional secretariat with governance structures in place, enabling the Global TxDC to begin operating as a coordinated global platform;
- b) convene initial structured engagement between funders and developers, contributing to greater coherence and reduced duplication across the antiviral R&D ecosystem;
- c) lay the institutional foundations for the Global TxDC to progress towards full operational capacity when additional donors will have engaged and sufficient funding will be secured; and,
- d) reinforce the EU's contribution to global health security, through strategic support to a multilateral coalition aligned with EU and international preparedness objectives.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-26-80	Q4/2026	EUR 800 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG HERA	Unitaid

CP-CA-26-81 Strengthen Global Health Resilience through MCM Preparedness for Emerging Threats (DG HERA)

POLICY CONTEXT

Recent years have underscored the growing interconnectedness of global health risks and the strategic importance of strong, resilient, and cooperative global health systems that can absorb shocks. Health emergencies, including pandemics, antimicrobial resistance, and the health impacts of climate and environmental change, continue to pose significant challenges with cross-border consequences for societies, economies, and global stability.

In her 2025 State of the Union address³⁰⁰, the President of the Commission underlined the Union's ambition to take a leading role in global health by announcing the intention to present a new Global Health Resilience Initiative³⁰¹. Its adoption in May 2026, reflects the Union's commitment to strengthening global preparedness, prevention, and response capacities, and to promoting effective multilateral cooperation in the field of health.

At the same time, the global health landscape is undergoing significant change. Shifts in international engagement and financing, including the scaling back or discontinuation of certain global health programmes and evolving participation in multilateral health structures such as the WHO, have highlighted the need for renewed leadership, coordination, and sustainable approaches to global health cooperation.

Against this backdrop, the proposed action seeks to contribute to a more resilient, coordinated, and inclusive global health architecture in the field of MCM, and ultimately to pandemic preparedness and response. It aims to support international efforts and collective preparedness for current and future health threats in the field of MCM, while reinforcing the EU's role as a reliable and proactive partner in MCM related work for promoting global health.

The proposed action is envisaged to be implemented by the WHO, in cooperation with regional actors (e.g. Africa CDC). WHO is the most appropriate organisation to implement this action in view of its global mandate, technical expertise, and coordinating role in international public health. Its established capacity to support health systems strengthening, preparedness, and emergency response, together with its global reach and partnerships, makes it the most suitable entity to implement this action in accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522.

Where a contribution agreement cannot be concluded with the implementing partner identified above the Commission may also select different pillar-assessed partner(s) in accordance with the applicable rules. The selection shall take into account criteria including comparable experience and track record in implementing actions of a similar nature and scale; existing contractual or partnership frameworks with the Commission; and/or prior working experience with the Commission in the area(s) covered by this action.

For proposals under this action, and exceptionally, costs incurred as from 16 May 2026, corresponding to WHO's Ebola Bundibugyo PHEIC declaration, are eligible and may be declared even if the related activities have been implemented prior to proposal submission. This is essential, as activities under this action are expected to contribute and/or be piloted for the

³⁰⁰ [State of the Union 2025 - European Commission](#).

³⁰¹ [COM\(2026\) 197 final](#) - Communication from the Commission to the European Parliament and the Council: Reinforcing global health resilience amidst geopolitical change.

ongoing Ebola BDBV outbreak, building and reinforcing actions previously establish (e.g. support for the WHO Blueprint for Filoviruses).

This action contributes to the achievement of 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 defined in Article 4, points (b) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The action aims to support global efforts to strengthen health resilience and preparedness through coordinated international cooperation on medical countermeasures, capacity-building, and system strengthening, including to address pressing needs such as those linked to the Ebola PHEIC. It will focus on reinforcing collective abilities for the use of medical countermeasures to prevent, detect, and respond to emerging and cross-border health threats, while promoting coherence with existing global and regional frameworks, in line with the expertise of WHO and their global coverage.

Specifically, this action is expected to contribute to at least some of the following activities:

- Support global coordination of medical countermeasures in crisis times via the WHO's i-MCMs networks;
- Support independent, evidence-based assessments of local and regional ecosystems supporting medical countermeasures resilience, covering preparedness, research and development, manufacturing, delivery, and financing capacities;
- Increase MCM availability through procurement and stockpiling in regional hubs, such as in the Dakar Hub;
- Strengthen and sustain local and regional 'ever-warm' manufacturing and response facilities in low- and middle-income countries, including those supported through Union-backed initiatives, such as under the Team Europe MAV+ initiative³⁰²;
- Map and analyse global and regional MCM manufacturing capacities by producing a comprehensive, geo-referenced dataset and gap analysis, as well as develop a standardised database for comparing manufacturing readiness across regions, covering scalability, bottlenecks, and response timelines;
- Support standing coordination platforms and crisis-ready playbooks as regards MCM preparedness linking EU institutions, WHO, regional organisations, and global partners to enable rapid alignment and decision-making during emerging health threats; and/or,
- Facilitate scenario-based preparedness and readiness exercises to test and improve cross-border coordination for vaccines, diagnostics, and therapeutics;
- Reinforce local and regional preparedness and response against cross-border threats in the field of MCMs through e.g. the establishment of coordinated hubs for threat detection and/or development, validation, and/or procurement of tools and MCMs that can be easily deployed during crisis, such as point-of-care diagnostics.

Activities(s) should, where appropriate and feasible, integrate transversal considerations, including gender and minority gaps and broader health inequalities, while upholding human rights and building synergies with, and supporting, relevant Union policies and instruments.

³⁰² [Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa - International Partnerships.](#)

Other activities in the area of MCMs preparedness in line with the Global Health Resilience Initiative might be envisaged, such as the development and/or validation of pathogen agnostic platforms for surveillance, or activities on other MCM, such as vaccines or therapeutics, contributing to the 100 Days Mission.

EXPECTED RESULTS AND IMPACT

The action is expected to strengthen global health preparedness and resilience while reinforcing cooperative, inclusive, and rules-based approaches to addressing cross-border health threats through medical countermeasures. By supporting effective multilateral engagement and internationally agreed norms, it will contribute to a stable and predictable global health environment and enhance the Union's role as a reliable and constructive global partner.

In detail, this action is expected to contribute to:

- Improved international coordination and coherence in MCM preparedness and response efforts;
- Increased availability of MCMs in Africa;
- Strengthened institutional and systemic capacities to prevent, detect, as well as develop, validate, and respond to health emergencies/or procure MCMs;
- Increased resilience and sustainability of the whole MCMs chain in partner countries and globally.

While this action is focused on MCMs, it will also contribute to enhanced visibility and credibility of the Union as a leading global health actor through partnership-based engagements; and reinforced commitment to multilateral cooperation, international norms, and rule-based approaches in global health governance.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Indicative budget
CP-CA-26-81	Q4/2026	EUR 5 070 800
Procedure type	Implemented by	Implementing entity
Indirect management	DG HERA	WHO

CP-CA-26-82.1 & 82.2 Global Health Financing Tracker for transparency and accountability (DG SANTE and DG HERA)

POLICY CONTEXT

Efforts to track financing for pandemic preparedness and response ('PPR') and other global health matters remain fragmented across countries, multilateral development banks, public development banks, and private actors. Existing financing instruments and reporting systems have been insufficiently utilised to systematically identify priority gaps, transparently track spending, and assess whether investments are aligned with agreed PPR and other benchmarks.

This fragmentation limits countries' ability to plan, compare performance, and mobilise timely support where financing gaps are emerging.

In its 2025 report '*Closing the Deal: Financing Our Security Against Pandemic Threats*'³⁰³, the G20 High-Level Independent Panel on Financing Pandemic Preparedness and Response highlighted the urgent need for a clear, standardised, and transparent approach to tracking pandemic-related spending. The Panel recommended the launch of an annual Global Pandemic Spending Tracker, analogous to the OECD development assistance dashboards and the regular publication of NATO defence expenditure data, to enable consistent benchmarking and peer comparison.

This action will therefore support the operationalisation of this recommendation by launching a tracker covering country-level, multilateral, and private-sector financing across health, security, and development budgets. By improving visibility of domestic and external PPR and other health spending, such a tracker would support countries in identifying priority gaps, enable external partners to target resources more effectively, and strengthen global accountability for pandemic preparedness activities and global health actions. It is expected that this action leverages on already existing global funding tracking platforms, such as GLoPID-R ('*Pandemic PACT Pandemic Analytical Capacity & Funding Tracking Programme*')³⁰⁴, which is focused on new or re-emerging infectious diseases research and innovation contributions, and other initiatives such as the G20 Mpox Financing Tracker.

This action one of the flagship initiatives included in the Commission's Global Health Resilience Initiative³⁰⁵, and is expected to support a stronger regional and global collaboration to standardise PPR and other global health financing, data collection, and economic assessments, thereby advancing collective health security and other global health objectives.

The Organisation for Economic Co-operation and Development ('OECD') is uniquely positioned to develop a Global Health Financing Tracker due to its global legitimacy, institutional neutrality, and proven expertise in tracking and analysing large-scale public and development financing. Its established data infrastructures, methodological standards, and convening power ensure transparency, comparability, and accountability across countries and funding instruments, supporting evidence-based decision-making and strategic alignment of global preparedness investments, making it the most suitable organisations to manage this action in accordance with Articles 7(1) and 13(1), point (b), of Regulation (EU) 2021/522. The World Health Organization and the World Bank will be closely associated with this action, contributing with their respective expertise to the Global Health Financing Tracker.

Where a contribution agreement cannot be concluded with the implementing partner identified above, the Commission may also select different pillar-assessed partner(s) in accordance with the applicable rules. The selection shall take into account criteria including comparable experience and track record in implementing actions of a similar nature and scale; existing contractual or partnership frameworks with the Commission; and/or prior working experience with the Commission in the area(s) covered by this action.

³⁰³ [Closing the Deal: Financing Our Security Against Pandemic Threats.pdf](#).

³⁰⁴ [Closing the Deal - Financing our Security Against Pandemic Threats \(G20 HLIP Report, November 2025\)](#).

³⁰⁵ Communication from the Commission to the European Parliament and the Council: Reinforcing global health resilience amidst geopolitical change, COM/2026/197 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52026DC0197>.

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 contributes to the achievement of 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 defined in Article 4, points (b) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to strengthen transparency, accountability, and evidence-based decision-making in global health financing by establishing a standardised system to track and disseminate information on funding flows, specifically by:

- establishing a Global Spending Tracker covering domestic and external PPR and other global health financing from countries, regional entities, multilateral and public development banks, and private actors;
- supporting tracking spending across health, security, and development budgets against a set of minimum financing benchmarks, wherever appropriate;
- harmonising reporting standards and methodologies for financing, drawing on existing international organisations expenditure tracking approaches;
- reducing reporting burden and improve data quality national and international digitalised financial and health information systems; and
- producing comparable analyses and public dashboards to support peer benchmarking, gap identification, and targeted financing decisions globally.

EXPECTED RESULTS AND IMPACT

The action is expected to improve the visibility and effectiveness of global health financing, advancing collective health security and global health goals, specifically by delivering:

- increased transparency and accountability of global health funding flows across domestic and international actors, contributing to improved coordination and alignment of financing for global health and pandemic preparedness and response;
- strengthened national and regional capacity to track and manage health spending using digitalised systems; and,
- more efficient and better-targeted investments based on comparable data, economic assessments, and shared evidence, contributing to stronger global health resilience and security.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Indicative budget
CP-CA-26-82.1 CP-CA-26-82.2	Q4/2026	EUR 500 000 EUR 500 000
Procedure type	Implemented by	Implementing entities
Indirect management	DG SANTE, DG HERA	OECD

CP-CA-26-90 Supporting ECDC activities to strengthen whole genome sequencing for EU preparedness and response (DG HERA)

POLICY CONTEXT

The COVID-19 pandemic highlighted the critical importance of genomic surveillance and rapid pathogen characterisation for detecting emerging variants, monitoring transmission dynamics, and informing timely public health responses. Whole Genome Sequencing ('WGS') has since become an essential component of infectious disease surveillance, supporting the early detection of outbreaks, the monitoring of antimicrobial resistance, and the identification of emerging or re-emerging pathogens. These capacities are closely linked to the development, procurement, and deployment of medical countermeasures, ensuring that emerging threats can be met with timely, coordinated, and effective responses across the Union, in line with DG HERA's mandate.

At EU level, strengthening genomic surveillance capacity across Member States has been recognised as a key priority to enhance preparedness and response to serious cross-border threats to health, as set out in Regulation (EU) 2022/2371 on serious cross-border threats to health. The integration of genomics into routine surveillance systems also contributes to supporting more coordinated and data-driven responses to infectious disease threats.

The European Centre for Disease Prevention and Control ('ECDC') plays a central role in coordinating genomic surveillance activities across the EU/EEA, including through guidance development, surveillance networks, training initiatives, the promotion of data sharing and interoperability, and coordination with the EU Reference Laboratories (EURL). Given ECDC's expertise in this area, this activity aims to support activities related to applied genomic epidemiology including bioinformatics and data integration, interpretation and sharing at EU level. This activity should leverage and build on relevant existing EU-funded projects, such as DURABLE and WGS direct grants to Member States.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The focus of this action is to support activities to sustain and improve national public health WGS capacity, complemented where relevant by RT-PCR workflows, and to consolidate further integration of genomics-based methods into routine disease surveillance and outbreak preparedness and response. In particular, the main objective is building workforce capacity and promoting knowledge exchange by:

- a) delivering targeted training for laboratory, bioinformatics, microbiology, and epidemiology staff to maintain and strengthen competencies, in coordination with ongoing ECDC and EURL initiatives.
- b) organising capacity building and knowledge exchange activities such as technical meetings, twinning visits, and other to share best practices and standard operating procedures across the end-to-end workflow, in coordination with ongoing ECDC and EURL initiatives.

EXPECTED RESULTS AND IMPACT

Through coordinated training, technical exchanges, and collaboration with ECDC and relevant EU networks, the action will reinforce workforce competencies and promote harmonised practices across the EU. In particular, it is expected to:

- a) strengthen competencies of laboratory, bioinformatics, epidemiology, and healthcare professionals in applying and integrating WGS data.
- b) increase knowledge exchange and collaboration between Member States through technical meetings, twinning visits, and sharing of best practices and standard operating procedures towards harmonised practices across the EU.
- c) improve integration of WGS and RT-PCR workflows into routine disease surveillance and outbreak response.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
CP-CA-26-90	Q4/2026	EUR 1 000 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG HERA	European Centre for Disease Prevention and Control

CP-CA-26-89 Contribution agreement with ECDC to support global health resilience (DG SANTE)

POLICY CONTEXT

In a changing geopolitical context, strengthening global health security and biodefence is important in protecting the Union's prevention, preparedness and response to cross-border health threats, including by forging collaboration with third countries and international partners to allow for the rapid detection, characterisation and response to emerging serious cross-border diseases and epidemics.

At the same time, gaps in capacities to address cross-border health threats persist and emerging threats require continuous vigilance and development of new capabilities, particularly in the area of biodefence and also at global level. It is essential to defend citizens in the EU, and across the world, against pandemics, climate-change related biological threats as well as unknown and novel health threats, such as AI-enabled biothreats, which can generate important political and economic impact. Such preventive action supports EU's strategic autonomy and competitiveness. This work requires forging stronger cooperation with third countries, well as international partner organisations, active in the field of health security, as well as strengthening expertise related to biodefence and biosecurity. Health security does not stop at the Union borders and there is a health security acquis, hence it is important to build capacity and ensure that national health security policies are aligned with Union actions in the candidate countries and potential candidates, and in other surrounding countries.

The European Centre for Disease Prevention and Control (‘ECDC’) has been working on cooperation with the public health actors in third countries, as well as international organisations competent in the field of public health, such as the WHO, hence contributing to the Union’s commitment to reinforcing partners’ preparedness and response capacity. Moreover, the ECDC has started getting involved in the area of biodefence and the possible intentional release of novel pathogens and AI-enabled biological threats.

Given the importance of strengthening the global collaboration on health security resilience, organisations such as national and regional centres for disease prevention and control are critical partners in this context. Hence, strengthening Union relations and work with other CDCs is crucial for health security preparedness and will also contribute to the implementation of the Global Health Resilience Initiative adopted by the Commission in May 2026.

In this respect, ECDC is expected to further strengthen collaboration with the United States Centers for Disease Control and Prevention, the Public Health Agency of Canada, the Chinese Center for Disease Prevention and Control, the Secretariat of Health of the United Mexican States, the United Kingdom Health Security Agency, the Korea Disease Control and Prevention Agency, the Japan Institute for Health Security, the Africa Centres for Disease Control and Prevention, ASEAN Centre for Public Health Emergencies and Emerging Diseases, Australian Centre for Disease Control, Caribbean Public Health Agency, Singapore Communicable Diseases Agency, Ministry of Health of Brazil, Israel Center for Disease Control and Gulf Center for Disease Prevention and Control.

In accordance with Regulation (EC) No 851/2004 amended in 2022 by Regulation (EU) 2022/2370³⁰⁶, the ECDC has established appropriate capacities to support international, cross-border interregional and field response, allowing it to mobilise and deploy outbreak assistance teams, known as the ‘EU Health Task Force’, to assist in local responses to disease outbreaks and collect field data. The Centre has created a permanent capacity to carry out missions in Member States, as well as in third countries, and to provide science-based recommendations on response to health threats.

In the effort to strengthen Europe’s responses against cross-border health threats, public health microbiology laboratories are the first line of defence against health threats from communicable diseases, including rising multi-drug resistance of human pathogens. Adequate laboratory capacity is a critical component of preparedness as it allows for rapid detection of infectious diseases and identification of transmissible and novel agents. Supporting laboratory and surveillance capacities, including in the countries of our immediate vicinity is therefore in the interest of the Union, and in accordance with, in particular, Article 30 of Regulation (EC) No 851/2004, as it will allow for early warning and reaction to outbreaks and the emergence of novel agents even before they cross our borders.

This action should support the Union’s capacity to be better prepared and respond faster to tackle outbreaks by strengthening ECDC’s expertise in the area of biodefence and biosecurity and by expanding ECDC’s collaboration with national and regional centres for disease prevention and control to facilitate the flow of information, with the WHO’s Global Outbreak Alert and Response Network to support rapid international response, and with national

³⁰⁶ 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 314, 6.12.2022, p. 1, ELI: <http://data.europa.eu/eli/reg/2022/2370/oj>.

reference laboratories in human health in candidate countries and potential candidates by extending to them the possibility to partake in microbiology laboratory activities.

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 preparedness 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

This contribution agreement is structured along three main strands of work, which complement each other:

1) Forging stronger collaboration with other regional and national Centres for disease prevention and control in third countries

Under this strand, ECDC is expected to foster bilateral cooperation with other CDCs and multilateral collaboration through a global network of CDCs. Through these channels of cooperation ECDC will, for example, facilitate information exchange and expertise, host study visits and organise staff exchanges, support the organisation of global simulation exercises, deliver training, foster joint deployments in outbreak situations etc., towards strengthening global health security.

2) Respond faster and more effectively to outbreaks by expanding the work of the EU Health Task Force to support rapid international response through stronger collaboration with the Global Outbreak Alert and Response Network.

Under this strand, ECDC is expected to engage in collaboration activities with WHO's Global Outbreak Alert and Response Network to respond to outbreaks, support global training activities, exchange of expertise, etc. ECDC is also expected to contribute to deployments to third countries for the purposes of rapid outbreak response, through the EU Health Task Force.

3) Contribute to strengthening surveillance and microbiology laboratory capacities, including in candidate countries and potential candidates.

Under this strand, ECDC, will be implementing its specific mandate in the area of surveillance and microbiology, which is to 'strengthen the capacity to diagnose, detect, identify and characterise infectious agents which have the potential to threaten public health', including for emerging and novel threats. As health threats do not know borders, ensuring adequate laboratory capacity and skills in countries bordering and across the Union are of crucial importance to ensure prevention, preparedness and early response in case of need.

EXPECTED RESULTS AND IMPACT

The expected results include:

- cooperation activities with regional and national Centres for disease prevention and control in third countries.
- active contribution to WHO's Global Outbreak Alert and Response Network, such as joint trainings and deployments.
- participation of candidate countries and potential candidates in microbiology laboratory activities.
- enhanced knowledge and expertise of ECDC in the area of biodefence and biosecurity, including in the area of new technologies.

Through the above results, this action is expected to have a positive impact on global health security, biodefence and resilience, forging closer multilateral cooperation with third countries and partner organisations. It should contribute to the strengthened capacity of the Union to withstand major global health threats, protecting EU citizens and the EU strategic autonomy and competitiveness.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
CP-CA-26-89	Q4/2026	EUR 1 656 903
Procedure type	Implemented by	Implementing entity
Indirect management	DG SANTE	European Centre for Disease Prevention and Control

CR/CV&NCD-CA-26-85 European guidelines and quality assurance scheme for cervical cancer (DG SANTE)

POLICY CONTEXT

The Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC³⁰⁷ was adopted on 9 December 2022. The new Council Recommendation is part of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan.

In addition to the cancer screening programmes for breast, colorectal and cervical as recommended under the 2003 Council Recommendation, the new Recommendation suggests screening for lung, prostate, and under certain conditions, gastric cancer, specifically in those countries with the highest gastric cancer incidence and death rates.

Through the Commission Initiatives on Breast and Colorectal Cancer, a system and streamlined methodology for the development of the European guidelines for cancer prevention, screening, and diagnosis and for the European quality assurance scheme covering the entire care pathway

³⁰⁷ [Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC \(OJ C 473, 13.12.2022, p. 1\).](#)

has been developed. Based on this existing methodology, guidelines for the screening of the other five cancer sites will be developed as indicated in the Recommendation. While work on breast and colorectal, as well as lung and prostate cancer are covered through activities funded under EU4Health Work Programmes 2023 and 2024, subsequent funding will be needed to continue the work done on cervical and gastric cancer. The initiatives on cervical and gastric cancer have been established through prior direct grants to the International Agency for Research on Cancer (EU4Health Work Programmes 2022 and 2024).

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

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of the action is to further develop the European guidelines and quality assurance scheme for cervical cancer prevention, screening and care, as part of the European Commission Initiative on Cervical Cancer (EC-CvC)³⁰⁸. The proposal for continued updating of the European guidelines and quality assurance schemes within the framework of EC-CvC will be a technical collaboration between the United Nations Population Fund (UNFPA) and the International Agency for Research on Cancer (IARC). The collaborative initiative between the two organisations, having a common mandate of supporting cervical cancer elimination, will promote evidence-based recommendations and standards in cervical cancer prevention across the EU Member States, candidate countries, and potential candidates.

The ongoing EUCervScreen QA project³⁰⁹, that this action will build on, has already published a first set of recommendations, and further development and updating will be needed.

The action will include the following activities:

- expansion of the European Commission Initiative on Cervical Cancer Working Group (expert panel) with the necessary profiles needed to cover additional topics for the upcoming activities ;(diagnosis and management of pre-malignant lesions for cervical cancer, screening and diagnosis of cervical cancer);
- further development of the European Cervical Cancer Guidelines with recommendations for prevention, diagnosis of pre-malignant lesions, and surveillance screening;
- further development of European Quality Assurance (QA) Scheme for Cervical Cancer Care Services, e.g. manuals and tools, in response to the guidelines' development sand in view of the completion of the European QA scheme prepared for the fit-for-the-purpose evaluation process by the European cooperation for Accreditation.

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

- final list of healthcare questions selected for guideline development related to cervical cancer prevention, screening and diagnosis;
- publication on the JRC website of evidence-based guidelines and their recommendations based on the GRADE Evidence to Decision Framework and informed by systematic reviews of the evidence;

³⁰⁸ [European Commission Initiative on Cervical Cancer | Cancer Screening, Diagnosis and Care.](#)

³⁰⁹ [EUCervScreen QA - Public Health - European Commission.](#)

- development, evaluation, rating and definition of requirements and indicators according to established criteria and methodologies and informed by systematic reviews of the evidence; and
- European Quality Assurance Scheme prepared for fit-for-the-purpose evaluation process by the European cooperation for Accreditation.

The approach will follow the methodology adopted under the EC Initiatives on Cancer Screening and Care (European Commission Initiative on Breast Cancer, European Commission Initiative on Colorectal Cancer, and others) overseen by the Commission's Joint Research Centre.

EXPECTED RESULTS AND IMPACT

The expected results and impact are:

- European Quality Assurance Scheme for Cervical Cancer Care Services manual ready for endorsement by the European cooperation for Accreditation.
- Up-to-date European cervical cancer guidelines with additional recommendations on cervical prevention (including HPV vaccination), screening and diagnosis of pre-malignant lesions; published on the JRC web-hub.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
CR/CV&NCD -CA-26-85	Q4/2026	EUR 2 000 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG SANTE	United Nations Population Fund (UNFPA)

HS-CA-26-86 Electronic Product Information for medicinal products (DG SANTE)

POLICY CONTEXT

Today, there is no harmonised regulatory-approved electronic product information³¹⁰ ('ePI') for medicines in Europe. An ePI will benefit public health as it will provide access to up-to-date information on a medicine's safety, benefits and conditions of use and will enable availability of the right information at the point of need.

³¹⁰ A medicine's product information (PI) includes the summary of product characteristics (intended for healthcare professionals), labelling (outer and inner packaging information) and package leaflet (for patients / consumers and generally included as a printed copy in the medicines package). It is a pivotal source of regulated and scientifically validated information that assists healthcare professionals in prescribing and dispensing the medicine and informs patients and consumers about its safe use.

The goal of the ePI project is to develop tooling, guidance and business processes to enable integration of ePI creation, management, publication and update into routine regulatory procedures for EU medicines.

The development and implementation of ePI support the Pharmaceutical Strategy for Europe³¹¹. In particular, Article 63 of the proposed Directive³¹², which states that the package leaflet shall be made available by the marketing authorisation holder in the packaging in paper format and electronically, and Member States may decide that the package leaflet shall be made available by the marketing authorisation holder for specific categories of medicinal products or for all medicinal products, only electronically.

This action follows action HS-CA-25-92 from the 2025 EU4Health work programme and the successfully completed actions HS-g-22-17.08 and HS-CA-24-51, from the 2022 and 2024 EU4Health work programmes respectively, which provided financial contribution to finance the ePI for medicinal products through contribution agreements.

The actions from 2022 and 2024 provided funding for the completion of a so-called ‘minimum viable product’, which was used in a pilot that took place between June 2023 and July 2024 in collaboration with National Competent Authorities from Denmark, the Netherlands, Spain and Sweden. During the pilot, ePI was successfully created in live regulatory procedures for real centrally authorised and nationally authorised medicines. Analysis of pilot outcomes resulted in recommended actions to enable introduction of ePI into routine business.

The aim of this specific action is to support the implementation of the go live of ePI.

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 Welfare³¹³.

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 (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.

The action covers all EU human medicines, including both centrally authorised and nationally authorised products, and applies to all product information components: the Summary of Product Characteristics (SmPC), the Package Leaflet (PL), and labelling. Contributions will come from regulators, marketing authorisation holders, healthcare professionals, patients and

³¹¹ 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](#).

³¹² 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](#).

³¹³ [Mission letter](#) to Commissioner for Health and Animal Welfare.

caregivers, while veterinary medicines are currently out of scope and may be considered for inclusion in the future.

OBJECTIVES, SCOPE AND ACTIVITIES

Objectives:

- a) ongoing development of functionalities identified as essential in the 2023-2024 pilot at EMA and four Member States (Denmark, the Netherlands, Spain, Sweden);
- b) transition into phased implementation, where ePI can be submitted by companies in their regulatory procedures and the authorised ePI data will be available for dissemination;
- c) development of functionality to enable use of ePI 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;
- d) onboarding National Competent Authorities and ensuring coordinated, phased implementation across the Union;
- e) 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:

The action will focus on activities that build on the technical and procedural learnings of the pilot project and will help with the onboarding of Member State authorities as well as iron out any technical hurdles which can open the way for a broader user base of ePI functionalities once the new pharmaceutical legislation applies:

- a) implementation of functionalities identified as essential for going live (versioning, import-export-import of ePI from stakeholder systems, linking ePI to ISO-IDMP³¹⁴ medicines data held by regulators, style guide and style sheet, and connecting ePI with other procedure management tooling);
- b) support development of Member States' requirements: importing and managing translated ePI, support mutual recognition or decentralised procedures, ensure ePI portal functionality is aligned with other national level business processes;
- c) performance and stability enhancements to prepare tooling for large number of users;
- d) change management activities: training and knowledge transfer to National Competent Authorities, planning coordinated roll-out across the EU.

EXPECTED RESULTS AND IMPACT

The expected results and impact of this action are:

- a) support for 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 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use³¹⁵;
- b) positive engagement with marketing authorisation applicants (e.g. in demos and user acceptance tests), giving pharmaceutical industry stakeholders the necessary evidence and confidence to invest resources and effort to support ePI implementation;

³¹⁴ Standards developed by the International Organisation for Standardisation (ISO) for the identification of medicinal products (IDMP).

³¹⁵ OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>.

- 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) advancing the 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 of patients, healthcare professionals, industry, EU/EEA countries, international level (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use);
- f) contribution to timely provision of the most up-to-date information on safe and effective use of medicines to patients and healthcare professionals in their preferred language and format;
- g) 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-26-86	Q4/2026	EUR 2 000 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG SANTE	Decentralised Agency (European Medicines Agency)

DI-CA-26-87 Strengthening health information systems in the European region through European Health Data Space and other EU principles and standards (DG SANTE)

POLICY CONTEXT

Regulation (EU) 2025/327 of the European Parliament and of the Council³¹⁶ (‘EHDS Regulation’) sets out a comprehensive framework for the use and reuse of health data across the Union. It establishes common standards in the EU for data quality, interoperability, and governance, ensuring that health data can be securely used and reused across borders.

More broadly, the European Health Data Space (‘EHDS’) aims at improving health care and advancing research and innovation, including artificial intelligence development, validation, and deployment, through common rules, standards, collaboration, and trust.

The EU Global Health Strategy (‘Strategy’)³¹⁷ promotes equity, resilience, and cooperation worldwide, tackling pandemics, climate-health links, and advancing universal health coverage. One of the objectives of the Strategy is to foster digitalisation as a fundamental enabler. To achieve this objective, it aims to display Union leadership by promoting standards, principles and expertise in health to shape the ongoing digital transformation globally. By setting

³¹⁶ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

³¹⁷ [EU Global Health Strategy](#).

benchmarks on privacy, access, and ethical use, the EHDS has the potential to shape global practices and inspire international approaches to trustworthy health data sharing.

Since 2022, the EU4Health Programme has supported the strengthening of health information systems in the European region with an action aimed at boosting health data governance and interoperability. There is a need to pursue these efforts, by further leveraging the EHDS as a driving force for digitalisation in the European region.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The main objectives of this action are to:

- a) ensure the continuation of the Health Information Network ('HIN'), established under the EU4Health action on "Strengthening health information systems by boosting health data governance and interoperability", establishing it as a platform for strategic engagement on digital health in Europe, in complement to the future EHDS governance, including on artificial intelligence ('AI'), other enabling technologies (telehealth, ageing in place, etc.), and themes (i.e. health equity, etc.);
- b) adapt or develop and deliver tools and capacity building activities (e.g. training materials, guidelines, etc.) to strengthen health information systems, support and promote the adoption of EHDS principles and standards in the wider European region, as well as promote discussions on the alignment of reporting indicators. Other areas may include health data standards (i.e. International Classification of Diseases-11) and will be identified by DG SANTE and the Health Information Network;
- c) advance AI adoption in the European region by aligning deployment partners practices (including regulatory) in the wider European region and, where relevant, other regions. This may be achieved through publications (i.e. reports, guidelines) and other tools (webinars, workshops, knowledge communities, etc.). This will also be achieved by contributing to and promoting the findings of ongoing and planned actions by the Commission including under the Apply AI Strategy (i.e. COMPASS AI³¹⁸, European AI-powered advanced screening centres³¹⁹);
- d) align with and complement other actions aimed at supporting or promoting the Commission's efforts on the implementation of the EHDS and promoting the uptake of AI solutions in health.

EXPECTED RESULTS AND IMPACT

The expected results are:

- a) a thriving platform for strategic engagement on digital health, where EU Member States and other European countries can discuss and exchange knowledge on health data governance and other digital health areas of interest;
- b) access by European healthcare and policy decision makers in the European region to tools and European healthcare and policy decision makers in the European region to tools and

³¹⁸ [Commission launches flagship initiative to increase use of AI in healthcare | Shaping Europe's digital future.](#)

³¹⁹ [https://digital-strategy.ec.europa.eu/en/policies/ai-screening-centres.](https://digital-strategy.ec.europa.eu/en/policies/ai-screening-centres)

training opportunities promoting EHDS adoption and alignment and other areas of interest identified;

- c) uptake of AI solutions for the delivery and organisation of care, supported by publications and other tools.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
DI-CA-26-87	Q4/2026	EUR 3 500 000
Procedure type	Implemented by	Implementing entity
Indirect management	DG SANTE	WHO

DI-CA-26-88 Economic modelling for the European Health Data Space and support to the uptake of Artificial Intelligence in health (DG SANTE)

POLICY CONTEXT

The adoption of Regulation (EU) 2025/327 of the European Parliament and of the Council³²⁰ ('EHDS Regulation') sets out a comprehensive framework for the use and reuse of health data across the Union. It establishes common standards in the EU for data quality, interoperability, and governance, ensuring that health data can be securely used and reused across borders.

More broadly, the European Health Data Space ('EHDS') aims at improving health care and advancing research, policy making and innovation through common rules, standards, collaboration, and trust.

Member States are now working on the implementation of the EHDS framework at national level. There is a need for economic models and strategies that could guide and stimulate investments needed, by showcasing benefits for the public and patients deriving from the introduction of EHDS and defining expected return on investments. These economic models and strategies are also relevant for driving the uptake of digital health technologies, such as artificial intelligence ('AI').

AI has the potential to dramatically transform healthcare systems and patient care, especially if the deployment of solutions in the clinic is successful. The Commission recently launched the Apply AI Strategy³²¹ with comprehensive measures to boost the uptake of AI across strategic sectors, also in healthcare, and actions supporting the validation and deployment of AI in healthcare, including a study which highlights the main challenges and opportunities for action. There is a need to make sure these actions and findings are broadly supported, promoted, and reinforced with inputs from and towards Organisation for Economic Cooperation and

³²⁰ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

³²¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0723>.

Development ('OECD') countries so they successfully shape policies and driving implementation in the Union and globally.

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

OBJECTIVES, SCOPE AND ACTIVITIES

The main objective of this action is to advance AI adoption in the European region by aligning deployment partners practices (including regulatory) in the wider European region and, where relevant, other regions.

The action will include the following activities for:

- a) designing and testing economic models and strategies evidencing the benefits and measuring the return on investment of the EHDS and digital health technologies (i.e. AI);
- b) advancing AI adoption in the European region by aligning deployment partners practices (including regulatory) in the wider European region and, where relevant, other regions. This may be achieved through the organisation of joint events and the publication of joint policy briefs;
- c) developing and promoting an analysis providing a deep understanding of the uptake of AI in health, looking at policies, as well as capturing the feedback from employers and employees.

This action should align with and complement other actions aimed at supporting or promoting the implementation of the EHDS and promoting the uptake of AI solutions in health under the Apply AI Strategy.

EXPECTED RESULTS AND IMPACT

The expected results are:

- a) the possibility for European healthcare decision makers to make better evidence-based decisions on the adoption and deployment of key initiatives and technologies, including AI, with the help of targeted governance and economic models and strategies;
- b) the possibility for the Commission, OECD and, where possible, other international organisations to provide their respective Member States with a comprehensive set of tools and analyses that can inform their efforts on advancing the uptake of AI in clinic.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Indicative call publication	Indicative Budget
DI-CA-26-88	Q4/2026	EUR 1 000 000
Procedure type	Implemented by	Implementing entity

Indirect management	DG SANTE	OECD
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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-26-01 Call for proposals on the European Hub for diagnostics development and scale-up (DG HERA)** – This action is open for participation without funding to entities from Switzerland and the United Kingdom. Their participation is justified by the need to ensure facilitated access to clinical specimens and reference panels for test validation, and manufacturing surge capacity for rapid production scale-up, which cannot be optimally satisfied with Union capabilities alone, given Switzerland’s unique infectious diseases’ diagnostics manufacturing landscape and the United Kingdom expertise in disease-agnostic platforms and outstanding research and biobanking facilities for high-risk pathogens, as well as frontier technologies for MCM development (e.g. AI-based).
- **CP-g-26-05 Direct grants to Member States' authorities to strengthen EU deployable diagnostic capacities and pre-positioned medical countermeasures for health emergencies (DG HERA)** – This action is open for participation without funding to entities from Albania, Canada, the United Kingdom, and Türkiye. Their participation is justified by the action's objectives, which envision alignment of rapid-response mobile laboratories ('RRML') deployment protocols with NATO standards. Therefore, the participation of these countries is necessary to guarantee interoperability of developed solutions from the outset, without which their field deployment in case of a health crisis will be impaired.
- **CP-g-26-07 Direct grant to Member States' authorities to enhance public health security in the Union (DG SANTE)** – This action is open to legal entities from Albania, Kosovo³²², Liechtenstein, Switzerland, Türkiye or the United Kingdom because the scope of the activities of this JA is not restricted to the Union or third countries associated to the EU4Health Programme, hence international cooperation may be sought with competent public health authorities of those countries. The participation of above entities is necessary for the achievement of the objectives of the action for the purpose of addressing cross-border health threats. Health security does not stop at the Union borders and there is a health security acquis, hence it is important to build capacity and get national health security policies aligned with Union actions in the candidate countries, and potential candidates, and in other surrounding countries.
- **CP-g-26-08 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 (DG SANTE)** – Open to laboratories that are legal entities from Albania, Kosovo, Liechtenstein, Türkiye and United Kingdom. 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

³²² This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

sought. Therefore, these laboratories being legal entities from Albania, Kosovo, Liechtenstein, Türkiye and United Kingdom may participate, upon request from the EURL(s), in activities of this grant at their own cost and will not be considered eligible participants or included in the grant agreement, either as beneficiaries or as associated partners. This 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-26-17 Direct grants to Member States’ authorities to support capacity building and AI capabilities in the EU medicines regulatory network, including implementation of innovative regulatory aspects of the new EU pharmaceutical legislation (DG SANTE)** – The objective of this action is to support the implementation of the Union’s pharmaceutical legislation which applies to all EEA countries, including Liechtenstein, which is also part of the European medicines regulatory network. It is thus in the Union’s interest to involve Liechtenstein in this joint action with the aim of harmonising implementation of the Union pharmaceutical acquis.
- **HS-g-26-22 Direct grants to Member States’ authorities to support reinforced market surveillance of medical devices and *in vitro* diagnostic medical devices to support effective and harmonised application across Member States (JAMS 3.0) (DG SANTE)** - The objective of this action is to support the implementation of the Union legislation on medical devices which applies to all EEA countries, including Liechtenstein. Therefore, it is in the Union’s interest to involve countries, including Liechtenstein, in this joint action to support the effective implementation of the Union’s medical device Regulations.

Actions open for participation with funding (Article 14(3) of Regulation (EU) 2021/522):

- **CP-g-26-03 Direct grant(s) to support pan-African health organisations to expand the Pathogen Genomics Initiative (‘PGI’) and related activities (DG HERA)** - This action is open for participation with funding to the Africa CDC and the Africa Society for Laboratory Medicine, both established in Ethiopia³²³, and the African Public Health Foundation established in Mauritius. Pathogen genomic sequencing and surveillance constitute critical pillars of global health security, enabling the early detection and characterisation of emerging pathogens, the identification of novel variants, and the timely informing of decision-making on medical countermeasures development and deployment. The African continent continues to represent a significant epidemiological risk zone for serious cross-border health threats, including the 2024 Mpox outbreak, or the ongoing 2026 Ebola Bundibugyo PHEIC. Furthermore, the continent has sustained the polio PHEIC since 2014 and faces an accelerating burden of antimicrobial resistance, which constitutes an ongoing and silent pandemic with direct implications for European health security. Given the dense intercontinental connectivity between Africa and Europe (including high-volume air travel corridors) pathogens emerged on the African continent represent a direct and credible threat to the health of the Union's population. This action therefore addresses an

³²³

It is important to highlight that Africa CDC operates through a decentralised regional structure, with offices in Egypt, Gabon, Kenya, Nigeria, and Zambia to ensure coordinated implementation and coverage across all regions of Africa. Where required by the legal or operational structure of ASLM, the participation of affiliated entities legally established in these or other African countries is allowed.

ongoing serious cross-border threat to health within the meaning of Article 3(1) of Regulation (EU) 2022/2371 and is accordingly eligible under Article 14(3) of Regulation (EU) 2021/522.

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

GRANTS

Crisis preparedness

- **CP-g-26-01 Call for proposals on the European Hub for diagnostics development and scale-up (DG HERA)**
Indicative budget: EUR 30 000 000
- **CP-g-26-07 Direct grant to Member States' authorities to enhance public health security in the Union (DG SANTE)**
Indicative budget: EUR 24 850 000

Health Promotion, Disease Prevention

- **DP-g-26-11 Direct grants to European Reference Networks (ERNs): support for the coordination, management, and operational activities of the ERNs (DG SANTE)**
Indicative budget: EUR 40 000 000

Cancer, Cardiovascular and other Non-communicable diseases

- **CR/CV&NCD-g-26-15 Call for proposals to support an EU flagship programme on cardiovascular diseases: a multidisciplinary and patient-centred approach to prevention, early detection, treatment and care (DG SANTE)**
Indicative budget: EUR 20 000 000

Health systems and healthcare workforce

- **HS-g-26-18 Call for proposal to support manufacturing capacity of critical medicinal products to strengthen the security of supply (DG SANTE)**
Indicative budget: EUR 40 000 000

PROCUREMENT

Crisis preparedness

- **CP-p-26-28 EU FAB - Ever-warm facilities for vaccines production (DG HERA)**
Indicative budget: EUR 165 000 000
- **CP-p-26-30 Support to speed up the development of, access to and/or uptake of medical countermeasures - MCM Accelerator (DG HERA)**
Indicative budget: EUR 86 000 000
- **CP-p-26-34 Purchase, innovation and deployment of medical countermeasures in emergency situations (DG HERA)**
Indicative budget for this thematic area: no budget allocated, however EUR 530 873 already allocated for hantavirus antiviral procurement (i.e. Favipiravir) in response to 2026 Andes Hantavirus outbreak. 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 the DG HERA's budget for 2026 as identified in table 3. In the recent past, a

similar action was performed with a budget of about EUR 46 000 000. 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 the Commission in its threat assessment.

ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT

Crisis preparedness

- **CP-CO-26-76 Support of innovative medical countermeasures with thematic innovation financial products by the European Investment Bank under the Invest EU Programme (DG HERA)**

Indicative budget: EUR 20 000 000