



# State of play: EU4Health Programme

ProMIS SUMMER SCHOOL 1 st Edition – 2021 “Health Sustainability: policies, funding, networks and European co-programming”

01.07.2021

*DG SANTE Dir A  
Giuseppina Luvarà  
EU4Health Task Force*

## EU4Health – the programme

*EU4Health is a clear message that public health is a priority for Europe and it is the instrument to pave the way to a European Health Union*

- **RESPONSE TO COVID-19** - supporting the fight against cross-border health threats and boosting the preparedness and capability to respond effectively to future health crises
- **AMBITIOUS VISION** – will go beyond crisis response to support and complement national health policies for strengthening and modernizing health systems, reducing inequalities and overcome shared challenges
- **THE LARGEST EVER EU INVESTMENT IN HEALTH** - over €5.3 bn (current prices) invested in health during the next 7 years (2021-27)



## EU4Health – financial envelope

*The financial envelope for the implementation of the Programme for the period 2021 - 2027 shall be:*



**EUR 5.3 billion in current prices**



- Min. 20 % reserved for health promotion and disease prevention actions
- Max. 12,5 % reserved for procurement complementing national stockpiling of essential crisis-relevant products at Union level
- Max. 12,5 % reserved for supporting global commitments and health initiatives
- Max. 8 % reserved for covering administrative expenses



26 March 2021

# Regulation (EU) 2021/522 – EU4Health Programme

- Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014



**Official Journal** L 107  
of the European Union



English edition      Legislation      Volume 64  
26 March 2021

---

Contents

1 Legislative acts

REGULATIONS

★ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (1) ..... 1

## EU4Health – general objectives

*EU4Health will provide the means and the instruments for delivering on the EU Health policy. Four general objectives represent the breath and the ambitions of the programme:*



- **Improve & foster health in the Union**



- **Protect people from serious cross-border health threats**



- **Improve access to medicinal products, medical devices, crisis-relevant products**



- **Strengthen health systems**



## EU4Health – general objectives

*EU4Health will be implemented along ten specific objectives that identify key areas of intervention*



- Disease prevention & health promotion;
- International health initiatives & cooperation.



- Prevention, preparedness & response to cross-border health threats;
- Complementing national stockpiling of essential crisis-relevant products;
- Establishing a reserve of medical, healthcare & support staff.



- Enhancement of availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant products



- Strengthening health data, digital tools & services, digital transformation of healthcare;
- Enhancing access to healthcare;
- Developing and implementing EU health legislation and evidence-based decision making;
- Integrated work among MS health systems.

# EU4Health – Synergies & complementarities with other EU Programmes

*In order to optimise the added value and impact from investments funded synergies will be sought in particular between the Programme and other Union programmes, to maximise those synergies and avoid duplications*



## EU4Health work programme 2021 – procedure leading to adoption

### THE COMMISSION:



- **PREPARATION** – prepares the strategic orientations, priorities and the draft annual work programme.



- **CONSULTATION, INPUT, INFORMATION** – consults the Member States, dialogues with stakeholders, including representatives of civil society and patient organisation on priorities, strategic orientations and needs, and informs the European Parliament.



- **ADOPTION** – of first annual work programme 2021 including actions, indicative budget allocation, deadlines and details for funds applications.

# EU4Health work programme 2021 – adoption

*Commission Implementing Decision of 24.06.2021 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 2021 (C(2021)4793 final).*

**DATE OF ADOPTION: 24 JUNE 2021**

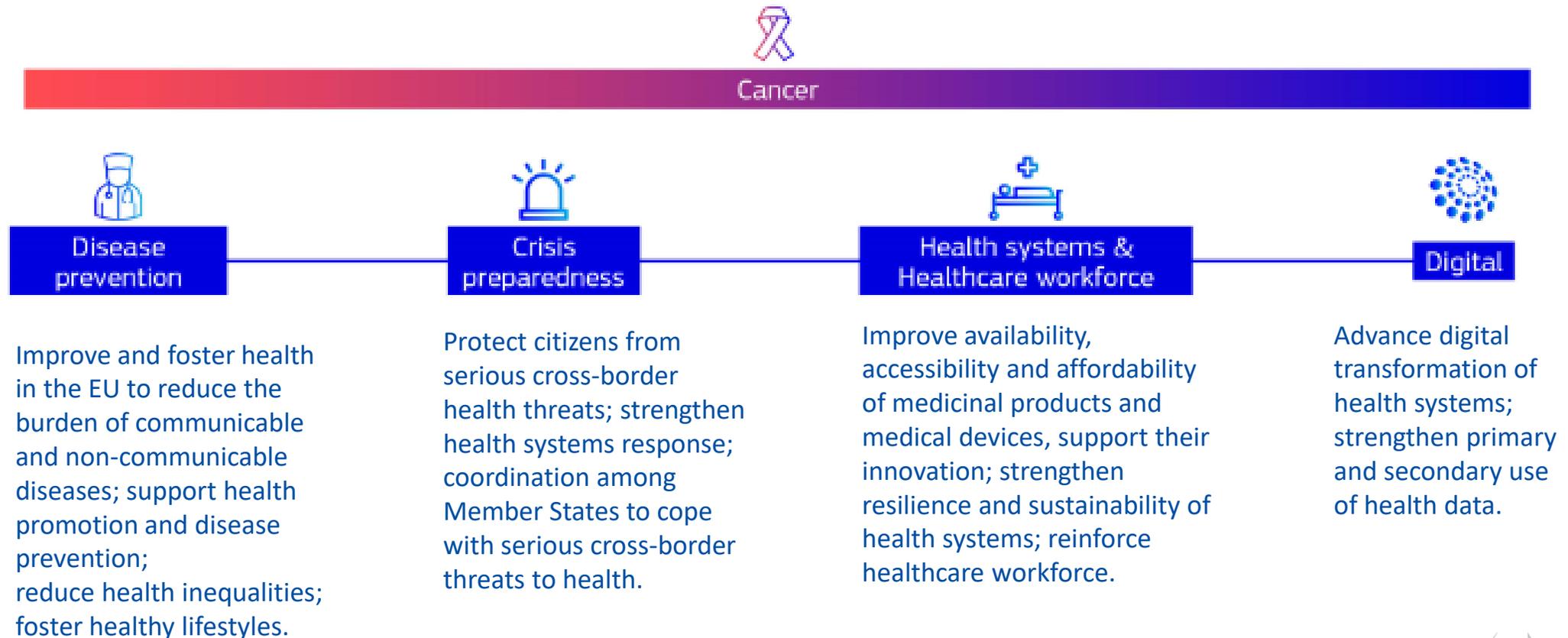
**BUDGET FOR IMPLEMENTATION OF THE 2021 PROGRAMME IS EUR 311 000 000.**

## **Annex to the Commission Implementing Decision – 2021 work programme**

Sets out the **priorities** and **actions** for 2021, including resource allocation, for the implementation of the EU4Health Programme.

## EU4Health work programme 2021 – strand of actions

*EU4Health supports a broad range of actions under four overarching “strands” with a cross-cutting focus on cancer*



# EU4Health work programme 2021 – actions

## The fight against COVID-19 pandemic

- Cross-border health threats
- Preparation of HERA

## EU health legislation

- Tobacco
- Blood, tissues & cells
- Medicines
- Medical Devices



## Pharmaceutical Strategy for Europe

- Medicines shortages
- Quality of medicines

## Europe's Beating Cancer Plan

- Flagship initiatives

**A policy implementation tool for both legislative and non-legislative initiatives.**

# 2021 Work programme: Strand 'Crisis preparedness'

Allocated budget: €107 million



## • *Priorities*

- Mitigate shortage of medicines and support expedited assessment of clinical trials for COVID-19 therapeutics
- Communicable diseases: surveillance systems requirements, early detection, risk assessment
- Support to the implementation of the 2017 EU One Health action plan
- EU Immunisation Initiative
- EU preparedness: Capacity and capability assessment and training programmes for health specialists
- AMR – Preparation of HERA

## • *Specific Actions*

### • **Joint actions (examples):**

- To monitor and mitigate medicines shortages by supporting national authorities;
- COVID-19 therapeutics clinical trials: coordinated assessment and reduction of the time needed to authorise;
- Communicable disease risk assessment and response: support implementation of digitalised, integrated surveillance systems at national and EU level for better detection of early signals.

### • **Action grants (examples):**

- AMR: support of capacity building, training and implementation of enhanced infection prevention and control practices.

### • **Procurements (examples):**

- Preparation of the European Health Emergency Preparedness and Response Authority (HERA) – mapping of medical countermeasures; assessing flexible EU manufacturing and innovation of medical countermeasures for serious cross-border threats to health; feasibility study on AMR stockpiling.
- Vaccine misinformation counter initiative; support Member States on national vaccination plans.

# 2021 Work programme: Strand ‘Disease prevention’

Allocated budget: €101 million



## • *Priorities*

- Health promotion and prevention of non-communicable diseases (NCDs) and communicable diseases.
- Sustainable cancer prevention.
- Improving early detection of cancer.
- Ensuring access to high standard cancer care diagnosis and treatment.
- Improving the quality of life for cancer patients, survivors and carers including reducing inequalities in cancer care and childhood cancers.

## • *Specific Actions*

- **Joint actions (examples):**
  - transfer and implementation of best practices on prevention of NCDs and related risk factors.
  - support to Member States to roll-out HPV vaccination.
  - creation of an EU Network of Comprehensive Cancer Centres.
- **Action grants (examples):**
  - support implementation of best practices on the ground to tackle mental health challenges during COVID-19).
  - design, planning and roll-out of an HPV campaign at Member State level.
  - ‘Healthylifestyle4All’ initiative.
  - ‘EU Cancer Treatment Capacity and Capability Mapping’ project.
  - EU Network of Youth Cancer Survivors
- **Direct grants to International Organisations (examples):**
  - collection and support for implementation of innovative best practices and research results on NCDs (OECD).
  - revision and update of the European Code against Cancer (WHO-IARC).
- **Procurements (examples):**
  - Analysis in the area of access to quality and safety in the use of medical radiation applications.
  - Development of an IT tool for a ‘Cancer Survivor Smart Card’.

## 2021 Work programme: Strand 'Health systems'



Allocated budget: €68 million

### • *Priorities*

- Improving access to healthcare and effectiveness of health coverage (vulnerable groups and targeted intervention)
- Strengthening the 4<sup>th</sup> cycle of the State of health in the EU
- Transfer of best practices in primary care
- Forecasting and planning for workforce in the health care sector
- EU Health System resilience testing and support programme
- ERN on urogenital disease and conditions
- Technical assistance and support to Orphanet

### • *Specific Actions*

- **Joint actions (examples):**
  - transfer and implementation of best practices in primary care and reinforce MS capacity.
  - Increase MS administrative capacity building in effective health workforce
- **Action grants (examples):**
  - Support to specialised healthcare for rare urogenital conditions and new guidelines, best practices, educational programmes and training
  - Integration of the Orphanet nomenclature and orphacodes in the new IT of the ERNs
- **Direct grants to International Organisations (examples):**
  - Recommendations and policy assistance to MS to close gaps in access to healthcare, addressing long-term challenges due to ageing (WHO regional Office for Europe).
  - Expanding the Country profile, stepping up the Voluntary exchanges, digitalisations of the deliverables (OECD and EU Observatory).
  - Resilience testing methodology and technical support to MS to regularly review the health crisis preparedness and to check their resilience against high-pressure scenarios and long-term structural challenges (OECD and EU Observatory).
- **Procurements (examples):**
  - ERN, IT infrastructure on Health Technology regulation

## 2021 Work programme: Strand 'Health systems'



### • *Priorities*

- Improving quality, safety and availability of Substances of Human Origin (SoHO)
- SoHO: Resilience, continuity of supply and access to safe and high quality therapies, including in crisis
- Safety, quality and efficacy of therapies in the field of assisted reproduction and base don haematopoietic stem cells
- Promoting quality of medicines: training, joint audits, inspection to ensure compliance with GMP and GDP
- Environment risk assessment for medicinal products
- Safety assessment cooperation and facilitated conduct of clinical trials
- Implementation of medical devices and in vitro diagnostics

### • *Specific Actions*

- **Joint actions (examples):**
  - Improving compliance with Union Pharma legislation, strengthening the inspectors capacity, assure quality of active ingredients imported from third Countries.
  - Building up and harmonisation of MS resources and expertise and effective and timely implementation of a coordinated safety assessment between Member States.
- **Action grants (examples):**
  - Good practice and guidance, monitoring, more sustainable supply system for access to essential SoHO therapies and access
  - New and update digital registries for good quality of data collection on therapies
- **Direct grants to International Organisations (examples):**
  - Maintain/update technical guidance, exchange of good practices, analyse annual collection of vigilance data (Council of Europe/EDQM).
- **Procurements (examples):**
  - Development of EUDAMED database, support of Union reference laboratories
  - Training scheme for MS on ENV risk assessment and training for SoHO inspectors and assessors.
  - Increase laboratory capacity COVID-19 convalescent plasma.

# 2021 Work programme: Strand 'Digital'

Allocated budget: €33 million



## • *Priorities*

- European Health Data Space (EHDS): primary use of health data – infrastructure governance
- EHDS: secondary use of health data – infrastructure governance

## • *Specific Actions*

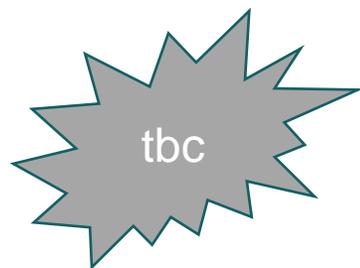
- **Joint actions (examples):**
  - Enlargement of the geographic coverage and scope of the MyHealth@EU Digital Service Infrastructure (eHDSI).
  - Enabling patient access to the eHDSI.
  - Increase health data semantic interoperability and build national capacity on health terminologies.
- **Action grants (examples):**
  - Pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes.
- **Procurements (examples):**
  - Support services for development, deployment and operation of infrastructures and IT systems enabling access to health data for secondary use

## EU4Health – Implementation

*The Programme may provide funding in any of the forms laid down in the Financial Regulation, in particular in the form of grants, prizes and procurement.*

### “other”

*possible forms of funding as allowed by the Financial Regulation*



### “Prizes”

*Contests to promote achievements of policy objectives of the Union where one or several beneficiaries are awarded a financial price following a evaluation*

### “Public procurement”

*Contracts with economic operators to purchase services or goods on the account of the Commission, either through open tendering procedures or the use of existing framework contracts which were established following competitive procedures*

### “Grants”

*Direct financial contributions from the European Union budget awarded to beneficiaries engaged in activities that serve Union policies.*

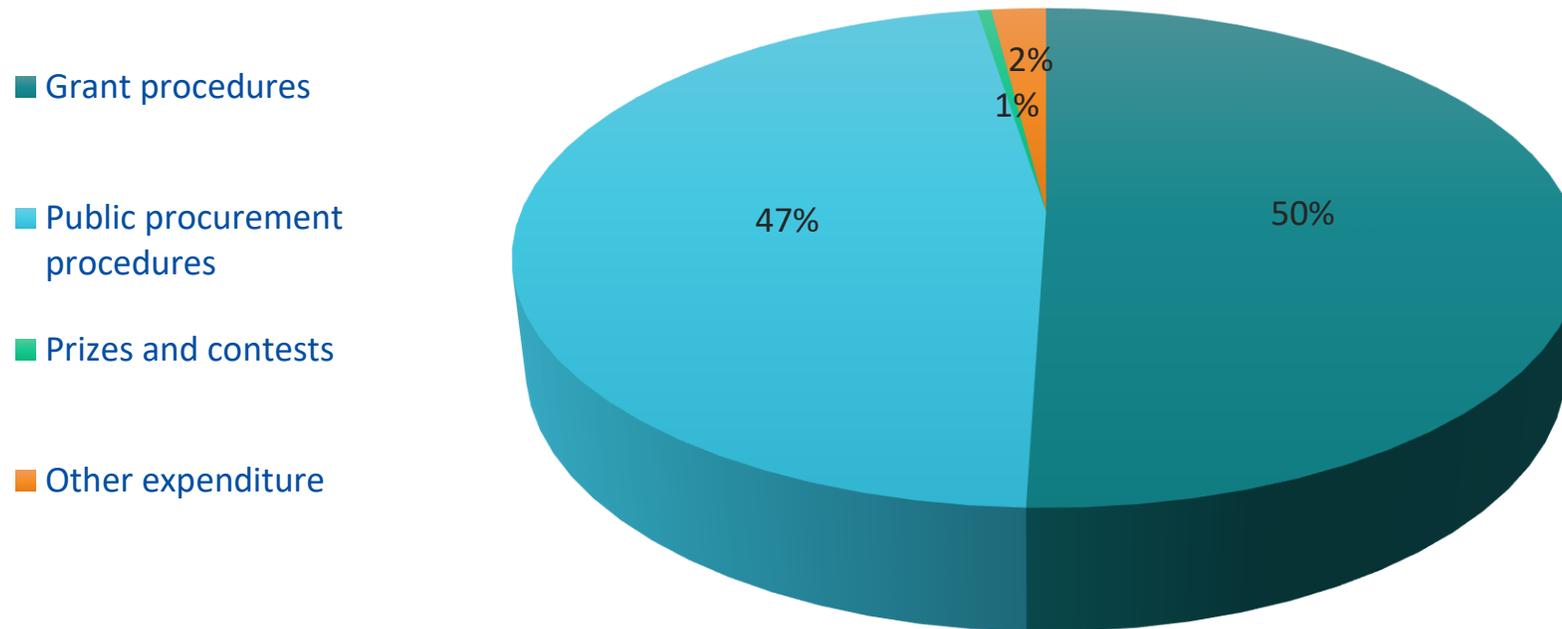
*Guiding principles:*

- *Equal treatment and transparency*
- *Co-financing by the beneficiary and non-profit rule applicable*
- *Non-cummulative, non-retroactive and absence of double financing*

## EU4Health – 2021 Budget allocation

*EU4Health will be implemented by annual work programmes*

Overall budget 2021: approx. 311 Mio €



## EU4Health - eligible entities

Any legal entity established in a Member State or an overseas country or territory linked to it and any legal entity created under Union law or as an international organisation

Any legal entities established in a third country associated with the Programme or non-associated (exception)

Any legal entity established in a third country listed in the annual work programme in accordance with the specific rules of the EU4Health Regulation

Natural persons are not eligible for grants under the EU4Health Programme!

## EU4Health – European Health and Digital Executive Agency (HaDEA)

The **European Health and Digital Executive Agency (HaDEA)** will be responsible for the implementation of the vast majority of the EU4Health programme budget (in coordination with the Commission).



**16<sup>th</sup> February established** ; fully operational later in the year and will have a strong financial control and management structure as we already had in place for the previous health programmes.

HaDEA's ambition is to help rebuild a post-COVID-19 Europe at its heart which will be greener, more digital and more resilient for future challenges.

# Calls for action grants

- Calls published on the EU portal on 25 June: Funding & tender opportunities/**Single Electronic Data Interchange Area (SEDIA)**.  
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities>
- Planned opening date: 29 July 2021
- Deadline date: 5 September 2021 17:00:00 Brussels time

# Five Calls for action grants

1. Action grants on substances of human origin (SoHo) - Increase resilience, ensure continuity of supply and access to safe and high quality therapies, in particular in times of crisis
2. Action grants for a project on the quality and safety of radiation technology in diagnosis and treatment of cancer
3. Action grants on collection tasks in relation to updating the European Cancer Information System to monitor and assess cancer screening programmes
4. Action grants for inter-speciality cancer training programme
5. Action grants for the EU Network of Youth Cancer Survivors

# Other Grants

- Joint actions:

for the first wave: nominations will open on 1 July and close on 31 August.

for the second wave: nominations will open on 20 September and close on 29 October.

- The direct grants to international organisations are on the pipeline

# Thank you

Contact: [SANTE-CONSULT-EU4HEALTH@ec.europa.eu](mailto:SANTE-CONSULT-EU4HEALTH@ec.europa.eu)



© European Union 2020

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

