

EU4Health Programme: strategic orientations and implementation

26 April 2021

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Health & ICT – funding programmes session ERRIN European Regions Research and Innovation Network





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







Spending parameters...



EUR 5.1 billion (2018 prices) EUR 316 million in 2021, rising to over EUR 900 million in 2027

Spending parameters for overall spending during the upcoming 7-year period:

- Minimum of 20% for health promotion and disease prevention;
- Maximum of 12.5% for procurement to complement national stockpiling of essential crisis relevant products;
- Maximum of 12.5% for supporting global commitments and international health initiatives;
- Maximum of 8% for administrative expenses





Programme Objectives



General:

> Improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases

- Protecting citizens from serious cross-border health threats
- Improving the availability, accessibility and affordability of medicinal products and medical devices and crisis relevant products
- Strengthening health systems by improving their resilience and resource efficiency



Programme Objectives



Specific:

- Improving and fostering health in the Union
 - Disease prevention & health promotion (includes Cancer)
 - International health initiatives & cooperation
- Protecting citizens from serious cross-border health threats
 - Prevention, preparedness & response to cross-border health threats
 - Complementing national stockpiling of essential crisis-relevant products
 - Establishing a reserve of medical, healthcare & support staff
- > Improving the availability, accessibility and affordability of medicinal products and medical devices and crisis relevant products
- Strengthening health systems by improving their resilience and resource efficiency
 - 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





Governance



- EU4Health Steering Group (consultation) Member States
- Stakeholders all relevant (input)
- European Parliament ENVI committee (presentation)
- **EU4Health Programme Committee** (comitology; opinion; yes) Member States
- European Commission (decision; implementing act)



Processes



The Commission **prepares**:

- ✓ strategic orientations, priorities and the draft work programme and adopts following consultation, input, information and positive opinion:
- √ first annual work programme 2021 including
 - actions
 - indicative budget allocation
 - deadlines
 - details for funds applications

Adoption expected during the <u>second quarter of the 2021</u> with a budget of around <u>€316 million</u>

European Commission

EU4Health work programme



A policy implementation tool for both legislative and non-legislative initiatives!

- The fight against COVID-19 pandemic
 - Cross-border health threats (directive)
 - HERA Incubator (communication)
- Europe Beating Cancer Action Plan (communication)
- Pharmaceuticals strategy (communication)
- EU health legislation (tobacco, blood, tissues & cells, medicines and medical devices, etc.)



2021 Work Programme



- The 2021 will be **the first Work Programme**, with number of notable features:
 - the budget is significantly smaller than for subsequent years;
 - ii. the first Work Programme will **at best be adopted in June 2021**, nearly half-way through the year; and
 - iii. the European Health and Digital Executive Agency (HaDEA) will be in its "start-up" phase.



Strategic orientations



Crisis preparedness

Disease prevention

Health systems and healthcare workforce

Digital

Cancer



Possible main priorities



- ➤ Crisis preparedness and management of cross-border health threats: Surveillance, preparedness and response; HERA (the EU BARDA) and the HERA Incubator; COVID-19 vaccines and new variants and public trust in immunisation; AMR; medicines shortages & security of supply
- ➤ Health promotion and disease prevention implementing Europe's Beating Cancer Plan; prevention of non-communicable diseases and related risk factors; tobacco control; mental health; transfer of best practices; health information
- ➤ Strengthening health systems and improve their resilience and resource efficiency: innovative care models; resilience testing methodology; planning & forecasting health workforce; ERNs
- > Digital transformation of healthcare and health systems: EHDS; health data
- > Strengthening the implementation of the health legislation: blood, tissue and cells, organs; medical device Regulation; in-vitro diagnostic; tobacco control and the pharmaceutical legislation.



Programme implementation



"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

"other"

possible forms of funding as allowed by the Financial Regulation



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

Health and Food Safety

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

Natural persons are not eligible for Programme!



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

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



The programming



The preparatory work is running in parallel to avoid delays:

- Member States:
 - informal EU4Health Expert Group (8 March)
 - Steering Group (23 April, end of April)
 - Programme Committee (June)
- > Stakeholders consultation/information (22 January, 24 March)
- ➤ Executive Agency European Health and Digital Executive Agency (HaDEA)
- > European Parliament EP ENVI Committee.





Roles



- The EU4Health Task Force in DG SANTE will
 - ✓ care of the preparatory work for the work programme,
 - √ facilitate the implementation of some actions
 - ✓ coordinate the implementation of the work programme with the executive agency
- The European Health and Digital Executive Agency (HaDEA) will be responsible for the implementation of the vast majority of the EU4Health programme budget.
 - ✓ 16th 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.
- The **Commission** will regularly monitor and evaluate the impact of the Programme against defined indicators, set out in the legal text.
- The Commission may develop **new indicators**, as necessary, including <u>at the level of the work programme</u> and its actions, which the beneficiaries will collect relevant data for the upcoming Programme reviews.

Thank you

https://ec.europa.eu/health/funding/events/ev_20210324_en

https://ec.europa.eu/health/funding/events/ev 20210122 en



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