EU4Health Programme: *legal overview and programming 2021*

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Web-Infoday EU4Health Programme 2021-2027

Italian Ministry of Health - webinar

Regulation (EU) 2021/522 – EU4Health Programme

26 Mach 2021

- 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

EUR-Lex
Access to European Union law

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Contents

I   *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

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EU4Health – the programme

EU4Health is a clear message that public health is a priority for Europe and it is the instrument to build the foundation for stronger, more resilient and accessible health systems

- **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** - 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 €5.7 bn (current prices) invested in health during the next 7 years (2021-27)

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EU4Health – financial envelope

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

EUR 2 446 000 000 in current prices

EUR 2 900 000 000 in 2018 prices

EUR 5.7 billion (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

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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**

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EU4Health – general objectives

EU4Health will be implemented along <u>*ten specific objectives*</u> *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.

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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 <u>consultation</u>, <u>input</u>, <u>information</u> and <u>positive opinion</u>:

✓ 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>

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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:

    i.   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.

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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)
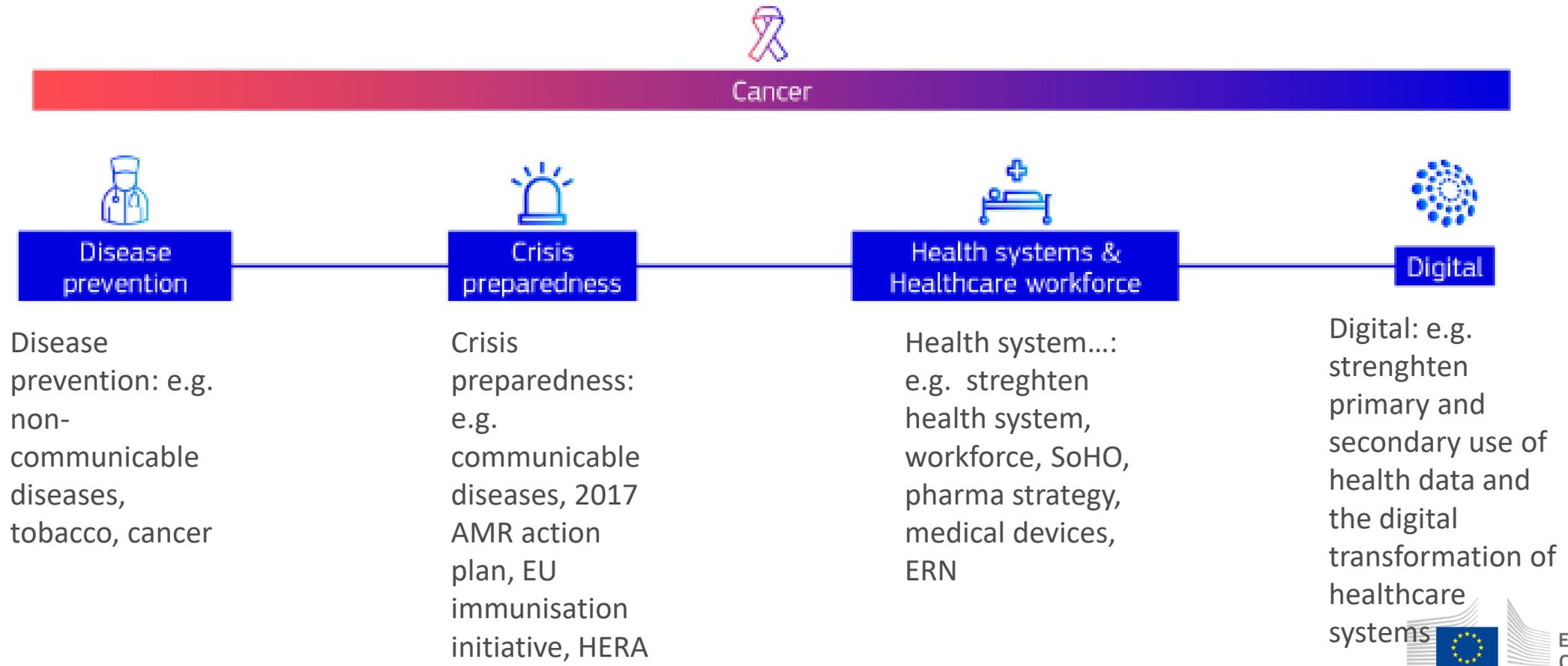
    ➢ Programme Committee (June)

➢ **Stakeholders** – consultation/information (22 January, 24 March)

➢ **Executive Agency** – European Health and Digital Executive Agency (HaDEA)

➢ **European Parliament** - EP ENVI Committee.

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EU4Health work programme 2021 – strand of actions

*EU4Health supports **a broad range of actions** under four overarching "strands" and Cancer as cross-cutting strand*

Cancer

Disease prevention	Crisis preparedness	Health systems & Healthcare workforce	Digital

Disease prevention: e.g. non-communicable diseases, tobacco, cancer

Crisis preparedness: e.g. communicable diseases, 2017 AMR action plan, EU immunisation initiative, HERA

Health system...: e.g. streghten health system, workforce, SoHO, pharma strategy, medical devices, ERN

Digital: e.g. strenghten primary and secondary use of health data and the digital transformation of healthcare systems

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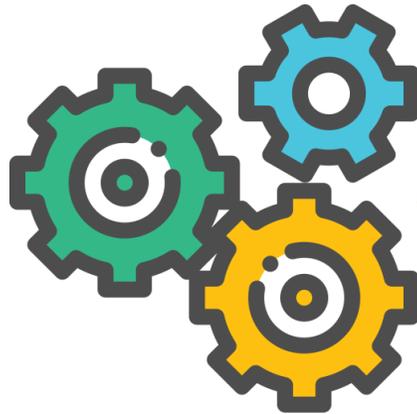
Possible main priorities

➢ 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*

EU4Health – Implementation

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

"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.
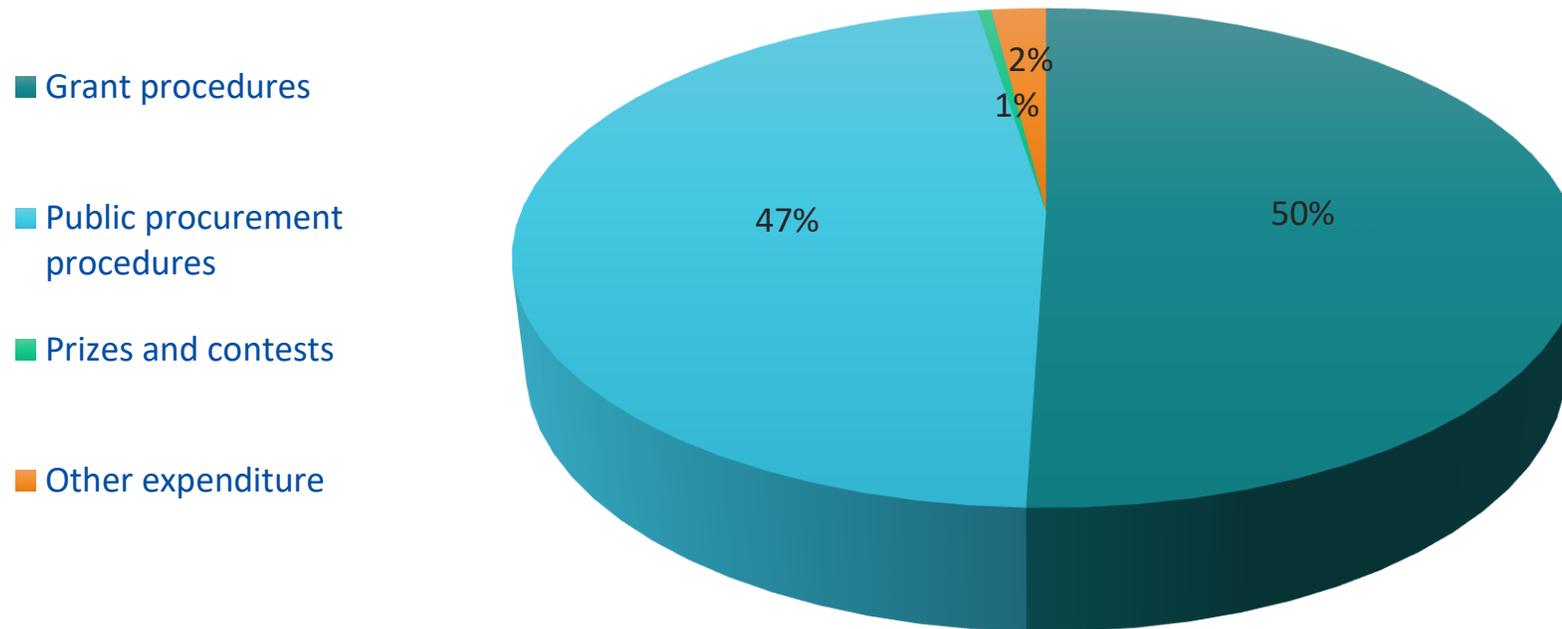
Guiding principles:
- *Equal treatment and transparency*
- *Co-financing by the beneficiary and non-profit rule applicable*
- *Non-cumulative, non-retroactive and absence of double financing*

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EU4Health – 2021 Budget allocation

EU4Health will be implemented by *annual work programmes*

Overall budget 2021: approx. 311 Mio €

- ■ Grant procedures
- ■ Public procurement procedures
- ■ Prizes and contests
- ■ Other expenditure

50%
47%
2%
1%

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!

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EU4Health – Synergies & complementarities

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 – status and timeline

- **atypical programming** *(few months instead of 1-2 years preparations)*

- **lower budget** *comparing to next years*

- *new executive agency (HaDEA)*

- **programming steps***:*

  - *Completed: stakeholders input; steering group; info European Parliament*

  - *ongoing: Programme Committee*

- **adoption** *by the Commission (as early as end of June)*

- **first main call (June/July)***; second main call (September/October)*

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.
  - ✓ 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 at the level of the work programme and its actions, which the beneficiaries will collect relevant data for the upcoming Programme reviews.

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Thank you

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